switch is higher than a historical cohort of etanercept reference drug. This is expected, since it is a selected group of etanercept responders. The interpretation of the results should be cautious, since only few patients are included in this first analysis. A larger number of patients from other participating out-patient clinics is planned to be included.

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SAT0147

EFFECTS OF BIOLOGICAL DISEASE-MODIFYING ANTI-RHEUMATIC DRUG TREATMENT ON PHYSICAL ACTIVITY, MUSCLE POWER, AGILITY AND INHIBITION OF FALL IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: It has been demonstrated that biological DMARDs (bDMARDs) treatment rapidly improved sign and symptom in patients with rheumatoid arthritis (RA). Those were evaluated using composite measures or biomarkers in daily clinical practice or clinical studies. Although rapid improvement of composite measures or biomarkers is important in the treatment of RA, primary important goal of treatment is improvement of long term health-related quality of life (HR-QOL) [1]. HR-QOL is based on physical function such as muscle power and agility.

Objectives: This study investigated the efficacy of bDMARDs on physical function and fall risk in patients with RA.

Methods: Periodic evaluation of physical function by the staffs in rehabilitation center in our institute has been performed in addition to routine rheumatology evaluation (SDAI, biomarkers, mHAQ) in RA patient initiated their first bDMARDs treatment from Oct. 2015 to Feb. 2018. 47 cases was registered in total. Evaluation of physical function included evaluation of muscle power (grasping power [GP] and knee extension power [KEP]), agility (Time up and go test [TUG] and 10m walking time [10mW]) and questionnaire using mHAQ, portable fall risk index [2] and the 25-question geriatric locomotive function scale (locomo25) [3] at baseline (initiation of bDMARDs), 1month, 3months, 6months and 12months. Disease activity of RA (SDAI, CRPMMP-3) was evaluated at same time point. Although 26 cases have passed one year from initiation of bDMARDs treatment, 9 cases dropped out from evaluation of physical function due to stopping of bDMARDs treatment or patient's hope not to be evaluated on physical function or major joint surgery performed in patient which was influence physical function. Results of early 17 cases who completed evaluation at 12 months were investigated in this study.

Results: Baseline patients characteristics was as follow (n=17): mean age 59.1 years old, RA duration 13.7 years, Mean SDAI 19.6, mean CRP 1.9mg/dl. Used bDMARDs were tocilizumab in 5 cases, golimumab in 4 cases, etanercept in 3 cases, abatacept in 3 case, certolizumab in one case and infliximab-biosimilar in one case. Data is presents as mean values at baseline-1-3-6-12 months below. SDAI and CRP were significantly improved on and after one month (SDAI: 19.6-9.6-5.8-5.7-5.5, CRP [mg/dl]: 1.9-0.3-0.3-0.3-0.8). GP and knee extension power significantly improved on and after one months except KEP at 3 months (GP [kg]: 12.3-14.1-15.9-16.9-17.4, KEP [N/kg]: 2.6-3.1-3.1-3.4-3.5). TUG at 10mW significantly improved on and after one months except TUC at 3months and 10mW at 3 months (TUG [s]: 9.3-8.0-8.2-7.3-7.4, 10mW[s]: 8.3-7.7-7.5-6.9-6.8). MHAQ significantly improved on and from 6 months (0.46-0.33-0.19-0.20-0.12). Locomo25 significantly improved on and from 1 month (31.7-20.6-18.5-16.7-15.0). Portable fall risk index significantly improved at only 12 months (8.8-8.6-7.8-7.8-6.8).

Fig1. Mean values and p-value by bDMARDs Treatment in RA Patients

	Baseline	1 month	3 months	6months	12months
SDAI	19.6 (Cont.)	9.6 (<0.01)	5.8 (<0.01)	5.7 (<0.01)	5.5 (<0.01)
CRP (mg/dl)	1.9 (Cont.)	0.3 (<0.01)	0.3 (<0.01)	0.3 (<0.01)	0.8 (<0.01)
Grasping Power (kg)	12.3 (Cont.)	14.1 (0.049)	15.9 (0.01)	16.9 (<0.01)	17.4 (<0.01)
KEP (N/kg)	2.6 (Cont.)	3.1 (0.02)	3.1 (0.21)	3.4 (<0.01)	3.5 (<0.01)
TUG (second)	9.3 (Cont.)	8.0 (0.03)	8.2 (0.055)	7.3 (0.01)	7.4 (0.02)
10mW (second)	8.3 (Cont.)	7.7 (0.02)	7.5 (0.14)	6.9 (<0.01)	6.8 (<0.01)
mHAQ	0.46 (Cont.)	0.33 (0.12)	0.19 (0.02)	0.20 (<0.01)	0.13 (<0.01)
locomo25	31.7 (Cont.)	20.6 (0.03)	18.5 (<0.01)	16.7 (<0.01)	15.0 (<0.01)
Fall risk index	8.8 (Cont.)	8.6 (0.83)	7.8 (0.16)	7.8 (0.12)	6.8 (<0.01)

Data is expressed as mean (p-value). P-value was calculated using Wilcoxon signed-rank test between baseline and each month.

SDAI: simplified disease activity index, KEP: knee extension power, TUG: timed up and go test, 10mW: 10m walking time, mHAQ: modified health assessment questionnaire

Conclusion: Signs and symptoms of RA were rapidly improved after the initiation of bDMARDs treatment and improvement of physical function was also rapidly improved. The changes from baseline and one month were more drastic in composite measure or biomarker of inflammation than that in muscle power and agility in respect with p-values. Inhibition of fall were achieved 12 months after bDMARDs initiation. These results suggested that physiotherapy might play an important role in RA patients treated with bDMARDs to gain more rapid improvement of physical function.

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SAT0148

IMMUNOGLOBULIN A LEVELS IN ADDITION TO RHEUMATOID FACTOR PREDICTS REMISSION ACHIEVEMENT WITH ABATACEPT IN PATIENTS WITH EARLY RHEUMATOID ARTHRITIS

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Background: Biological disease modifying antirheumatic drugs (bDMARDs) now play an important role of clinical practice for patients with rheumatoid arthritis (RA). Abatacept (ABT) has a biologic agent that has an unique mechanism of action suppressing T lymphocyte activation. Although many prediction studies about therapeutic responses to bDMARDs for RA have been conducted to date [1], few studies has focused on ABT.

Objectives: The aim of this study was to identify predictive clinical biomarkers for remission achievement with ABT in RA patients.

Methods: We retrospectively reviewed consecutive patients with RA who started ABT from 2010 through 2018 in Keio University Hospital. We defined early ABT use as the initiation of ABT within two years from diagnosis without radiographic progression in hand X rays, and stratified the patients into the early ABT users and the late ABT users. Baseline characteristics were compared between patients who achieved CDAI remission achievement at 6 months and those who did not in both groups.

Results: One hundred and seven RA patients who were treated with ABT with baseline information available were enrolled in the study. Among them, 15 patients were classified into the early ABT users and 92 were the late ABT users, and the remission rates at 6 months were 40% and 24%, respectively. In the early ABT users, patients who achieved CDAI remission at 6 months showed significantly higher IgA levels than those who did not achieve remission (390 mg/dL vs 279 mg/dL, P=0.04, respectively). The difference in IgA disappeared in the late ABT users (332 mg/dL vs 313 mg/dL, P=0.60, respectively). Principal component analysis revealed that in the early ABT users, patients who

achieved remission and those who did not could be clearly separated by the levels of IgA, IgG, rheumatoid factor, and albumin (Figure), whereas those baseline characteristics were mostly overlapped in the late ABT users (cut-off value for predicting remission with sensitivity and specificity in the early ABT users; IgA 342 mg/dL with 83% and 100%, IgG 1880 mg/dL with 50% and 100%, rheumatoid factor 152 IU/mL with 50% and 100%, albumin 3.7 g/dL with 88% and 67%, respectively). The area under the curves of receiver operating characteristic curves to predict remission were 0.833 of IgA and 0.778 of rheumatoid factor titer.

Conclusion: We identified serum IgA titer was the novel predictive factor for response of ABT.

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Figure. Principal component analysis by clinical parameters. RF; rheumatoid factor, HAQ; health assessment questionnaire, EGA; evaluator's global disease activity, PGA; patient global assessment, VAS; visual analog scale

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SAT0149

EVALUATION OF A PROSPECTIVE COHORT EVENT MONITORING MODEL FOR PATIENT-REPORTED ADVERSE DRUG REACTIONS ATTRIBUTED TO BIOLOGICAL DMARDS: VALIDITY OF THE PATIENT-REPORTED INFORMATION AND REPRESENTATIVENESS OF THE PARTICIPANTS

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Background: To gain knowledge on the prevalence, course and treatment of adverse drug reactions (ADRs) attributed to biological DMARDs (bDMARDs) and the experienced impact of ADRs on patients, an ADR-focused online questionnaire system was developed by Netherlands Pharmacovigilance Centre Lareb (*Dutch Biologic Monitor*). 898 consecutive patients of eight centers who used a bDMARD indicated for an inflammatory rheumatic disease were followed between 1 January 2017 and 31 December 2018.

Objectives: Validation of the quality of the patient-reported information in the *Dutch Biologic Monitor* and evaluation of the representativeness of the participants in relation to the source populations.

Methods: Patients of 18 years and older who used a bDMARD indicated for an inflammatory rheumatic disease were included by the participating hospitals. The patient-reported medical information (bDMARD, indication and concomitant DMARDs) of 479 patients with a rheumatic disease (Reade, Amsterdam: N=174; Sint Maartenskliniek, Nijmegen: N=305) was verified by comparing the patient-reported parameters to the patient's electronic health record using percentage agreement and/or Cohen's kappa. Representativeness was tested in 550 patients with an inflammatory rheumatic disease (Reade, Amsterdam: N=192; Sint Maartenskliniek, Nijmegen: N=358) by comparing their grouped age, grouped gender and prescribed bDMARD to the source populations of the respective hospitals using Mann-Whitney U test, Chi-Square Goodness-of-Fit and Fisher's exact test with Monte Carlo simulation.

Results: 95.8% of the tested rheumatic disease patients correctly reported their bDMARD (active substance and brand name). Furthermore, agreement between patients and the electronic health record was strong for the reported indications (90.4% agreement; $\kappa = 0.832$) and moderate for the concomitant therapy (79.7% agreement; $\kappa = 0.725$). The subpopulations were representative for their source populations based on grouped gender (38.4% vs. 38.8% male, $\chi^2(df=1, N=550)=0.038$; $p>0.05$) and bDMARD use (both $p>0.05$). Grouped median age was not representative (58.0 vs. 56.0 years; $U=962872$; $p=0.04$), since the male participants were older (58.5 vs. 55 years; $p=0.001$).

Conclusion: So far, the *Dutch Biologic Monitor* seems to be a valid tool to obtain knowledge on ADRs attributed to bDMARDs, since the reported medical information corresponded to the patients' electronic health records and the participants generally represented their source populations regarding grouped gender and prescribed bDMARD.

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