In the group of pts treated with TOFA Δ NT-proBNP level significantly correlated with the percentage change in DAS 28 ($r=0.41, p=0.038$), there was no direct correlation with changes in the parameters of the LV diastolic function.

Conclusion: TCZ and TOFA treatment for 12 m reduced NT-proBNP levels in RA pts without clinically manifest CVD and CHF. Falling NT-proBNP concentrations are associated with positive dynamics of RA activity (DAS 28) and inflammatory markers (CRP, ESR), therefore allowing to suggest that increased NT-proBNP levels should be considered as a component of disease activity. Correlation between Δ NT-proBNP and Δ EeLF may be indicative as possible impact of these biomarkers on the LV diastolic function's development in RA pts.

Disclosure of Interests: None declared

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FRI0095

SARILUMAB IMPROVED PATIENT-PERCEIVED IMPACT OF RHEUMATOID ARTHRITIS WHATEVER THE BASELINE DISEASE ACTIVITY: FIRST RESULTS FROM AN INTERVENTIONAL NON CONTROLLED STUDY: SARI PRO, IN MODERATE AND SEVERE RHEUMATOID ARTHRITIS PATIENTS

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Background: Sarilumab, an anti-IL-6R antibody, is approved for the treatment of moderate to severe RA and shown efficacy on disease activity and patient-reported outcomes (PROs). Detailed analyses of drug efficacy from the patient point of view is important. SariPRO is a pragmatic interventional study close to the daily practice.

Objectives: To assess the effectiveness of sarilumab on several PROs using the RAID (Rheumatoid Arthritis Impact of Disease) score.

Methods: The SariPRO study (NCT 03449758) was a French multicenter interventional study assessing the effects of sarilumab 200 mg on PROs in patients with moderately to severely active RA with an inadequate response or intolerance to conventional synthetic or biologic DMARDs. The primary endpoint was change in total RAID score from baseline to week 24 (RAID ranges 0-10 where 10 is maximal impact). Changes from baseline for RAID, DAS28-ESR and CDAI according to baseline disease activity were analyzed as secondary outcomes. Safety was assessed by monitoring adverse events (AE). All statistical analyses were descriptive, 95% CI was given when appropriate.

Results: 84 patients were included in 31 centers and 62 were evaluable and analyzed for effectiveness. They had similar characteristics to the 84 patients at baseline and were as expected for an RA population initiating a biologic: mean (SD) age: 59.9 (12.4) years, 71.0% female, disease duration 9.7 (10.3) years, rheumatoid factor positivity 82.5%, ACPA positivity 86.4%, and DAS28=4.9 (11). Total RAID score decreased significantly from 5.7 (2.0) at baseline to 3.3 (2.5) at W24; mean change was -2.4 [95% CI: -3.0; -1.8]. Furthermore, this improvement was noted both for highly and less active patients at baseline: for patients with DAS28-ESR < 5.1 ($n=31$), mean change was -1.56 [-2.28; -0.83] and for patients with DAS28-ESR ≥ 5.1 ($n=27$), mean change was -1.98 [-2.91; -1.05]. Changes in DAS28-ESR and CDAI were significant (-2.8 [-3.2; -2.4] and -15.2 [-18.5; -11.8], respectively). AEs were consistent with the safety profile of anti-IL-6R antibodies and with results from RCTs (data not shown).

Conclusion: In this real world study, treatment with sarilumab during 24 weeks in RA patients led to an improvement in the total RAID score irrespective of baseline levels of disease activity. This is the first time RAID score is used as the primary endpoint in a study.

References:

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FRI0096

CLINICAL BENEFITS REPORTED IN AMPLE TRIAL OBSERVED IN A REAL-WORLD (RW) COHORT OF US RHEUMATOID ARTHRITIS (RA) PATIENTS

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Background: Efficacy observed in controlled trials may not reflect RW effectiveness, given documented differences in patient populations and management.¹

Objectives: This study aimed to assess disease measures over time as measured in a trial setting (AMPLE) and in a separate RW observational setting, both among patients with RA treated with abatacept.

Methods: The RW cohort comprised retrospective patient-level data abstracted by 31 community rheumatologists for adult RA patients treated with abatacept who had an anti-cyclic citrullinated peptide-2 titer ≥ 250 AU/mL. AMPLE was a phase III, randomized controlled trial of RA patients treated with abatacept that assessed disease measures over a 2-year follow-up. Data included demographics, treatments, labs, and disease measures (tender and swollen joint counts (TJC, SJC), C-reactive protein (CRP), American College of Rheumatology-20 (ACR20) and ACR50 at baseline and 3 and 6 months) and were summarized descriptively. Disease measures were evaluated across AMPLE and RW cohorts.

Results: Of the 291 RW patients and 318 AMPLE patients, the majority were female (70%, 81%), white (72%, 81%), and RF-positive (91%, 76%), respectively (Table 1). The mean ages at abatacept initiation were 54.7 and 51.4 years

Table 1: Patient Characteristics.

	RW cohort (n=291)	AMPLE cohort (n=318)
Female (n, %)	205 (70%)	259 (81%)
White (n, %)	209 (72%)	257 (81%)
Age at abatacept initiation, years (mean, SD)	54.7 (14.8)	51.4 (12.6)
RF-positive* (n, %)	249 (91%)	240 (76%)
Concomitant medications (n, %)		
Corticosteroids [†]	132 (45%)	207 (65%)
Methotrexate	179 (62%)	318 (100%)
Prior biologic use (n, %)	241 (83%)	0 (0%)
Route of administration (n, %)		
Intravenous	183 (63%)	0 (0%)
Subcutaneous	108 (37%)	318 (100%)

LEGEND: *among 274 with known RF status; [†]corticosteroids in AMPLE cohort at any time in the 2-year study period

old in RW and AMPLE, respectively. Concomitant corticosteroids (45%, 65%) and methotrexate (62%, 100%) were common in RW and AMPLE, respectively. All patients in AMPLE were biologic naïve, whereas 83% of RW patients had prior biologic use. AMPLE administered abatacept subcutaneously (SC), while 37% of RW patients received abatacept SC. Patients had median SJC and TJC of 6 and 8 in RW and 13 and 22 in AMPLE at abatacept initiation, respectively (Table 2). SJC (TJC) improved a median of 65% (60%) and 68% (66%) at 3 months and 75% (67%) and 76% (75%) at 6 months in RW and AMPLE, respectively (Fig 1). The majority of patients achieved ACR20 at 3 months (79% and 60%) and 6 months (88% and 66%) in RW and AMPLE, respectively, while 58% and 32% achieved ACR50 at 3 months and 67% and 45% at 6 months, respectively (Fig 2).

Table 2. Changes in Disease Activity.

	RW cohort (n=291)	AMPLE cohort (n=318)
SJC (median)		
Baseline value	6	13
3-month value	2	4
6-month value	1	3
TJC (median)		
Baseline value	8	22
3-month value	3	7
6-month value	2	5
CRP, mg/dL (mean)		
Baseline value	1.08	1.6
3-month value	0.47	0.8
6-month value	0.30	0.8
ACR20 achieved (n, %)		
3-month value	194 (79%)	191 (60%)
6-month value	78 (88%)	209 (66%)
ACR50 achieved (n, %)		
3-month value	144 (58%)	103 (32%)
6-month value	60 (67%)	144 (45%)

LEGEND: values soonest after 3 months and value between 6-9 months used for RW cohort; values at days 85 and 197 used for AMPLE cohort.

Conclusion: Despite differences in patient characteristics, improvements in SJC and TJC, as well as high rates of ACR20 and ACR50, were observed in both trial setting and RW settings. These improvements in disease activity were observed at similar magnitudes in both settings, demonstrating that trial efficacy is achievable in RW clinical practice with abatacept treatment.

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FRI0097

EFFECTS OF BIOLOGICAL DISEASE-MODIFYING ANTI-RHEUMATIC DRUG TREATMENT ON PHYSICAL ACTIVITY, MUSCLE POWER, AGILITY AND INHIBITION OF FALL IN PATIENTS WITH RHEUMATOID ARTHRITIS -THE 2-YEAR RESULTS

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Background: Treatment with biological DMARDs (bDMARDs) rapidly improves signs and symptoms in patients with rheumatoid arthritis (RA). The efficacy of these bDMARDs was evaluated using composite measures or biomarkers used in daily clinical practice or clinical studies. Although a rapid improvement in composite measures or biomarkers is important in the treatment of RA, the primary goal of treatment is improvement of long-term health-related quality of life (HR-QOL) [1]. HR-QOL is evaluated based on physical functions (PF) such as muscle power and agility. We reported the 1-year results of our study presented at EULAR 2019 [2]. The present study was conducted to investigate the 2-year results of our study by including more patients than those included in the previous one.

Objectives: This study was aimed at investigating the efficacy of bDMARDs with respect to PF and fall risk in RA patients.

Methods: At our institute, in addition to routine rheumatology evaluation, periodic evaluation of physical function is performed by staff members in our rehabilitation center in RA patients in whom the first bDMARD treatment was initiated in Oct. 2015–Feb. 2018. In total, 41 cases were registered in this study. Evaluation of PF included evaluation of muscle power [grasping power (GP) and knee extension power (KEP)]; agility [time up and go test (TUG) and 10-m walking time (10 mW)]; and a questionnaire using modified HAQ, portable fall risk index [3], and the 25-question geriatric locomotive function scale (locomo25) [4] at baseline (BL), which implies the time at the initiation of bDMARD treatment, i.e., 1, 3, 6, 12, and 24 months. Disease activity of RA was evaluated at the same time points. Although 2 years had elapsed from BL in 37 patients, 13 patients dropped out from the evaluation of physical function owing to cessation of bDMARD treatment, rejection of evaluation for physical function, or major joint surgery performed in a patient. The results of 24 patients who completed the evaluation at 24 months were investigated in this study.

Results: Baseline characteristics of the 24 patients were as follows: mean age 60.8 years, RA duration 12.3 years, mean SDAI 19.0, and mean CRP level 2.1 mg/dl. The bDMARDs used in the study were abatacept in 7 patients, adalimumab in 4 patients, tocilizumab in 4 patients, golimumab in 4 patients, etanercept in 3 patients, certolizumab in 1 patient, and an infliximab biosimilar in 1 patients. Data are presented as mean values at BL and at 1, 3, 6, 12, and 24 months (Fig.1). SDAI and CRP levels were significantly improved at and after 1 month. GP and KEP were significantly improved at and after 3 and 6 months. TUG and 10 mW results were significantly improved at and after 3 and 6 months. Modified HAQ results were significantly improved at and after 3 months. Locomo25 scores were significantly improved at and after 1 month. Portable fall risk index values were significantly improved at and after 12 months.