Abstract THU0153 – Figure 1. Bar graph demonstrating distribution of time (in months) to achieve first sustained remission

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THU0154 HIGH RESOLUTION COMPUTED TOMOGRAPHY (HRCT) OF THE LUNG IN PATIENTS WITH RHEUMATOID ARTHRITIS: PREVALENCE OF INTERSTITIAL LUNG DISEASE INVOLVEMENT AND DETERMINANTS OF ABNORMALITIES

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Background: Interstitial lung disease (ILD) causes significant morbidity and mortality in patients with rheumatoid arthritis (RA). An international consensus about the identification of a subgroup of RA-patients with an high risk to develop ILD is still lacking.

Objectives: To assess: (a) the prevalence of ILD involvement in RA on high resolution computed tomography (HRCT) scan; (b) the relationships between pulmonary function tests (PTFs), patient-centred measures and ILD, (c) the potential risk factors that contribute to ILD in RA-patients.

Methods: We retrospectively evaluated the data of RA patients afferent to an Italian rheumatological center from 1/1/2014 to 30/6/2018. We extrapolated clinical (age, gender, age at onset the RA), laboratoristic [rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPAs)], respiratory functional data [forced vital capacity (FVC) and single-breath diffusing capacity for carbon monoxide (DLco)], patient-centred measures of dyspnea (PCMD) (modified Borg Dyspnea Index and VAS for breathing), health assessment questionnaire-disability index (HAQ-DI), and HRCT. HRCT abnormalities were scored using a conventional visual reader-based score (CoVR)(1) and a computer-aided method (CaM)(2). The relationships among the two HRCT scores, PFTs and PCMD were calculated using Pearson's correlation. The AUC-ROC curve was calculated to determinate the discriminative performance of measures between patients with and without ILD. Multivariate regression model was used to assess the strength of association between ILD and RA features.

Results: 151 patients with RA were included (45 males and 106 females, mean age of 53.4 ± 7.6 years). We identified ILD in 29 of 151 patients (19.2%). Usual interstitial pneumonia was the most common pattern on HRCT. Patients with ILD were older ($p < 0.01$), their age at RA-onset and HAQ-DI were higher (respectively with $p < 0.01$ and $p < 0.05$) than patients without RA-ILD. RF positivity and titer were similar in the two groups, whereas ACPA positivity and titre were higher in ILD group ($p = 0.02$). Extent and severity of ILD, total CoVR and CaM score correlated closely with DLco and PCMD (both with $p < 0.0001$). A reduced DLco was the most sensitive test to predict the presence of ILD on HRCT (AUC-ROC, 0.811 ± 0.037). Multivariate analysis showed that older age ($p < 0.0001$), age at RA onset, ($p = 0.025$), ACPA titers ($p = 0.004$) and smoking habit ($p = 0.008$) were independent explanatory variables of HRCT damage.

Conclusion: ILD is a frequent feature of RA. RA-ILD is associated with age, age at RA-onset, smoking habit, and ACPA titer. DLco seems the most sensitive measure to predict ILD on HRCT scan, followed by PCMD.

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THU0155 PATIENT ADHERENCE WITH A SMARTPHONE APP FOR DISEASE MONITORING IN RHEUMATOID ARTHRITIS

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Background: Patients increasingly are asking for tools to improve self-management. Electronic patient reported outcomes (ePROs) transmitted digitally allow patients to both communicate with their clinicians between visits and help track their own disease activity. While several tools have been developed in rheumatology, few data have been reported regarding patient adherence.

Objectives: To examine patient adherence to a smartphone app for rheumatoid arthritis (RAapp).

Methods: We developed a smartphone app to deliver daily disease assessments to patients with RA (RAapp). The app was tested as part of a randomized controlled trial examining the potential clinical benefits of RAapp compared to a wait-list control. These analyses focus only on the adherence of patients who received RAapp and completed the 6-month trial. We recruited RA patients from the rheumatology practice at a large academic medical center in the US. Patients with at least 6 weeks of stable DMARD use who were at least 18 years of age were required to give written informed consent, be fluent in English, and have a smartphone with an iOS or android operating system. RAapp was downloaded by patients through a password protected link on to the patient's phone after consent. Patient's received daily notifications regarding disease

assessments, including disease activity (RADAI), function (MDHAQ), pain (PROMIS), fatigue (PROMIS), sleep (PROMIS), and depression (PROMIS). The current set of analyses focused on adherence to RAapp, overall, by scale, and over the 6 months of the trial. We examined adherence to RAapp over the duration of the study and examined factors related to adherence using mixed regression models. Factors tested included patient age, sex, educational attainment, and baseline CDAI.

Results: 75 patients received RAapp and have data included in these analyses (5 patients are in the last month of follow-up). 60 (80%) were female; age breakdown was 24% < 45 years, 49% 45-64 years, and 27% 65 years and over; and educational attainment was 19% high school, 59% college, and 23% beyond college. Baseline CDAI demonstrated 20% in remission, 45% low, 24% moderate, and 11% high disease activity. During the 6-month study, median adherence to the RAapp daily questionnaires was 81.6% (interquartile range 48.4% to 92.3%). Broken down by the type of questionnaire, median adherence was: disease activity 79.8%; pain 80.8%; mood 76.2%; function 79.3%; fatigue 77.0%; and sleep 77.8%. Adherence to the daily questionnaires was highest in the first month but decreased a small amount each of the following months (see Figure, p for trend < 0.001). The only significant predictor of higher adherence was age 65 or over ($p = 0.04$). High baseline CDAI was associated with a lower adherence but was not statistically significant ($p = 0.07$).

Conclusion: We developed and tested an ePRO app for RA (RAapp). Among a large group of patients, adherence to the app was good but declined slightly over time. There was no substantial variation in adherence with different ePRO scales. Older age was the only significant predictor of adherence.

Abstract THU0155 – Figure 1

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THU0156 NO CONFIRMATION OF INCREASED RISK OF IDIOPATHIC FACIAL NERVE PALSY UNDER TOCILIZUMAB

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Background: Spontaneous reports of nine facial paralyses and five facial pareses made by healthcare professionals from Europe have recently prompted EMA's Pharmacovigilance Risk Assessment Committee (PRAC) to consider a potentially increased risk of idiopathic facial nerve palsy for patients receiving tocilizumab.

Objectives: To assess whether this signal can be confirmed with data of a large data set with known denominators for various treatments, comparing the risk in patients receiving tocilizumab with the risk in patients receiving other DMARDs.

Methods: The German register RABBIT is a prospective longitudinally followed cohort of RA patients with a new start of a DMARD after at least one csDMARD failure. For this analysis, patients were included who were

enrolled with a biologic DMARD start between 01/2007 and 04/2018. DMARD specific, unadjusted incidence ratios were calculated.

Results: Between 2007 and 2018, a total of 20 facial nerve palsies (FNP) were observed in 11963 RABBIT patients, of those, three were excluded due to obvious reasons (e.g. stroke) leaving 17 idiopathic FNP. Three of them were observed in tocilizumab patients, leading to an incidence rate of 0.47 per 1000 PY (95% CI: 0.10, 1.14), which is higher than the incidence rate observed in patients receiving conventional synthetic (cs)DMARDs (0.21, 95% CI: 0.04; 0.51) but does not stand out among the incidence rates observed for other biologicals (see Table 1). The overall incidence of an idiopathic FNP among patients receiving (synthetic or biological) DMARDs was 0.37 (95% CI: 0.22, 0.57) which is higher than the incidence of idiopathic FNP in the general population (with 20-30 cases per 100,000 persons [1]). Age and gender were roughly equally distributed among patients with and without idiopathic FNP. Patients with idiopathic FNP had longer disease duration, more frequently presented with joint erosions and with prior treatment with biologics. They also had lower physical function and more comorbidities. In one patient with idiopathic FNP receiving treatment with Rituximab (original biologic) a Sjogrens' syndrome was reported as comorbidity, which is associated with an increased risk of neuropathies.

Conclusion: The overall incidence of idiopathic FNP among rheumatoid arthritis patients receiving DMARDs was higher than the incidence in the general population. However, an increased risk for patients receiving tocilizumab compared to patients treated with other biologicals cannot be confirmed. The incidence of idiopathic FNP is higher for patients receiving biologicals compared to patients receiving csDMARDs. This might be due to the higher disease activity. However, the small number of cases with an idiopathic facial nerve palsy is a limiting factor in analysing and interpreting these results.

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Abstract THU0156 –Table 1. Unadjusted incidence rates for idiopathic facial nerve palsies.

Drug	Number of events	Incidence rate (per 1000 patient years under treatment)	95% CI
csDMARDs	3	0.2	(0.0; 0.5)
Etanercept (original)	4*	0.7	(0.2; 1.6)
Etanercept (biosimilar, SB4)	1	1.9	(0.1; 6.9)
Golimumab	1	0.7	(0.0; 2.4)
Rituximab	5*	0.8	(0.3; 1.6)
Abatacept	1	0.3	(0.0; 1.2)
Tocilizumab	3	0.5	(0.1; 1.1)
All	17	0.4	(0.2; 0.6)

* One patient was exposed to both Etanercept (original) and Rituximab at the time of event.

Abstract THU0156 –Table 2.

Table 2. Baseline characteristics of patients with idiopathic facial nerve palsy (FNP) compared to all patients without the event.

Parameter	FNP	No FNP
N	17	11946
Age	60.6 (12.6)	57.5 (12.7)
Women	12 (70.6%)	8022 (67.2%)
Disease duration	14.7 (10.7)	9.4 (8.9)
Prior biologic therapies	1.4 (1.3)	0.5 (1)
RF or ACPA positive	14 (82.4%)	8701 (73.4%)
Joint erosions	10 (71.4%)	5753 (50.9%)
DAS28-ESR	4.8 (1.3)	4.9 (1.3)
ESR	29.1 (17.5)	28.9 (22.4)
CRP	15.8 (15.3)	14.4 (20.7)
% of physical function	55.3 (28.7)	65.4 (23.3)
Actual glucocorticoid therapy	14 (82.4%)	9380 (77.8%)
Actual glucocorticoid dose (mg/d)	9.8 (9.7)	8.9 (9)
Ever smoked	8 (47.1%)	6432 (56.9%)
Sjogrens' syndrome	1 (5.9%)	152 (1.3%)
Number of comorbidities	3.9 (3.3)	2.2 (2.2)

For continuous variables, mean and standard deviation are reported, while for categorical variables absolute numbers and percentages are reported.

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