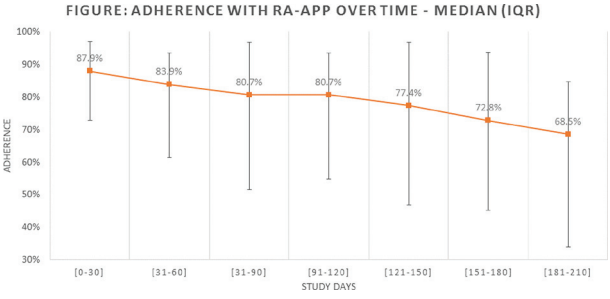
assessments, including disease activity (RADAI), function (MDHAQ), pain (PROMIS), fatigue (PROMIS), sleep (PROMIS), and depression (PROMIS). The current set of analyses focused on adherence to RAapp, overall, by scale, and over the 6 months of the trial. We examined adherence to RAapp over the duration 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 Sjoegrens' 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.

REFERENCE:

[1] Murthy, J.M.K., Saxena, A.B. (2011): Bell's palsy; treatment guidelines. Ann Indian Acad Neurol. 2011 Jul; 14(Suppl1): S70–S72.

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%)	8922 (74.7%)
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 (1.2)	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%)	9280 (77.8%)
Actual glucocorticoid dose (mg/d)	9.8 (9.7)	8.9 (9)
Ever smoked	8 (47.1%)	6432 (56.9%)
Sjoegrens' 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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THU0157 REASONS FOR NON-PARTICIPATION IN A RANDOMIZED CONTROLLED TRIAL COMPARING TWO SEASONAL INFLUENZA VACCINES IN RHEUMATOID ARTHRITISPATIENTS

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Background: Low recruitment rates (12%) into influenza vaccine studies are reported among healthy older adults. Fear of side effects, lack of insight into personal risk status, and doubts about vaccine efficacy are the most commonly reported reasons for non-participation[1]. Rheumatoid arthritis (RA) patients are also at high risk for influenza and benefit from yearly immunization[2]. A number of influenza vaccines are currently available; however, it is unknown which vaccine(s) provides optimal protection to RA patients. Estimating participation rates is key for designing studies to address that issue.
Objectives: To define the rate of non-participation and reported reasons for refusing entry into a randomized clinical trial (RCT) comparing two influenza vaccine formulations (NCT02936180 - ClinicalTrials.gov).
Methods: Seropositive RA patients from McGill University Health Centre, on stable treatment prior to recruitment ($\geq$3 months), were invited by their treating rheumatologists to participate in the study. A vaccine nurse contacted participants from Year 1 (Y1) and those from Year 2 (Y2) encountered a recruiter immediately after their rheumatologist's appointment. Patients who agreed to participate signed the consent form and were later contacted by a vaccine nurse to schedule their appointment. Reasons for non-participation were documented.
Results: Over two influenza seasons, 692 RA patients were invited to participate in the study. The non-participation rate was 59.5% (Y1=64.6%, Y2= 53.1%, p=0.1). Non-participants and participants did not differ in age or sex (age mean±SD: 61.7±14.7 vs 60.9 ±12.9, p=0.5; female sex%: 76.8 vs 79.9, p=0.33). Inclusion and exclusion criteria resulted in the loss of 17 (4.1%) and 19 (4.6%) subjects, respectively. The three most commonly reported reasons for non-participation were vaccine misconceptions (n=49, 20.4%), reluctance to participate in a clinical trial (n=35, 14.6%), and lack of available time (n=29, 12.1%). Thirty-one patients reported more than one reason for non-participation. Reasons for non-participation were similar according to sex and patient age (> or < 65 years).
Conclusion: Only half of eligible RA patients accepted to be enrolled in this influenza vaccine study. Enhancing patient literacy on vaccines and the relevance of conducting clinical trials is essential to optimize both recruitment to such trials and immunization rates.

REFERENCES:

[1] Allsup SJ, Gosney MA. Difficulties of recruitment for a randomized controlled trial involving influenza vaccination in healthy older people. Gerontology. 2002; 48:170–173.
[2] Blumentals WA, Arreglado A, Napalkov P, Toovey S. Rheumatoid arthritis and the incidence of influenza and influenza-related complications: a retrospective cohort study. BMC Musculoskelet Disord. (2012) 13:158.

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THU0158 IMPAIRED OLFACTORY FUNCTION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Recent studies indicated that rheumatic disorder can be associated with olfactory loss.
Objectives: To specifically investigate chemosensory function in patients with rheumatoid arthritis (RA) by valid and reliable psychophysical tests and compare them to healthy controls.
Methods: We investigated 212 RA patents (43 men, 169 women; mean age 59 years) and compared their results to 30 healthy controls (10 men, 20 women; mean age 40 years). All participants received standardized olfactory (odor thresholds, odor discrimination and identification for suprathreshold testing) and gustatory tests (taste sprays – suprathreshold taste function; taste strips – quasi-threshold gustatory test). In addition, blood chemistry was also assessed (e.g., for CRP, RA factors, and anti-CCP).
Results: RA patients rated their senses of smell and taste to be as good as that of controls. However, in RA patients 4% were found to be anosmic, and 36% to be hyposmic. These numbers were 0 and 20%, respectively, in controls. RA patients exhibited significantly lower scores in odor identification and discrimination. Gustatory test scores were also decreased in RA patients. No such differences were found for odor thresholds. Interestingly, the changes in olfactory and gustatory function neither correlated with disease duration nor with indicators of RA activity or severity like C-reactive protein, rheumatoid factors, anti-CCP antibodies orDAS28-Score. Moreover, there was no correlation between olfactory dysfunction and treatment with DMARDs, e.g. amount of MTX, or Tumor necrosis factor α inhibitors.
Conclusion: These results indicate that olfactory and gustatory function is significantly decreased in patients with RA. This decrease in function seems to be unnoticed by most patients which may be due to the fact that RA patients have no compete loss of function (anosmia), but still function in the range of hyposmia or even normosmia. Importantly, the changes in olfactory function are not observed at the level of odor thresholds but only for suprathreshsold tasks, which may suggest that the decrease in function is due to higher-order central-nervous processing of olfactory information. In addition, the lack of correlations between disease parameters and chemosensory dysfunction indicates that the decrease in chemosensory function may be a trait characteristic of RA patients.
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THU0159 RISK FACTORS FOR DEVELOPING SARCOPENIA IN PATIENTS WITH RHEUMATOID ARTHRITIS AT 2 YEARS: FROM THE CHIKARA STUDY

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Background: Patients with rheumatoid arthritis (RA) are at higher risk of sarcopenia due to joint dysfunction and chronic inflammation. The prospective observational CHIKARA study (Correlation research of sarcopenia, skeletal muscle and disease activity in rheumatoid arthritis; registration number UMIN000023744) was started in 2016 to clarify the correlation between RA disease activity and sarcopenia. We reported that glucocorticoid use and low body fat were independent risk factors for developing sarcopenia at 1 year in RA patients last year.
Objectives: Risk factors for sarcopenia were investigated over a 2-year period this time.
Methods: 100 patients (78 female, average age 68 years) enrolled in the prospective CHIKARA study underwent examinations of body composition (body weight, muscle mass, fat mass, predicted bone mass, etc.; measured by a body composition analyzer (MC-780A; TANITA, Tokyo, Japan)), laboratory data, disease activity, Health Assessment Questionnaire (HAQ), and treatment condition at baseline and at 2 years. Sarcopenia was diagnosed using the criteria of the Asia Working Group on Sarcopenia. Of 64 patients without sarcopenia at baseline, those who developed sarcopenia at 2 years were identified, and risk factors were investigated by univariate and multivariate analyses.
Results: Six patients (9.4%) developed sarcopenia during the 2-year follow-up. Glucocorticoid use >5 mg/day was significantly higher (p=0.009), and MMP3 (p=0.018) and HAQ (p=0.045) were significantly increased in the patients who developed sarcopenia during the 2-year follow-up. Sarcopenia development was significantly associated with male sex (r=0.28, p=0.03), age (r=0.27, p=0.03), glucocorticoid use >5 mg/day (r=0.33,