characteristics and the primary endpoint were tested using Cox proportional hazards regression.

Results: We identified 2851 RA patients of whom 1017 initiated a new csDMARD course requiring laboratory monitoring. Of these, 860 patients (58.9 years, 68% women, 65% seropositive) were included in the analyses after excluding patients with missing laboratory results (n=148) or elevated ALT at baseline (n=9). Of the 860 patients, 220 initiated two csDMARDs simultaneously [99% sulfasalazine (SSZ) and methotrexate (MTX)]. Primary endpoint was reached in 55 of 860 (6.4%) patients, including 10 who initiated two csDMARDs. Of these 55 patients, primary endpoint was reached in 40 of 55 (73%) patients during first three follow-up tests. In 31 of 55 (56%) patients, including 3 initiators of 2 csDMARDs, elevated ALT led to csDMARD cessation during the first 6 months. In Cox proportional hazards model with age, sex, seropositivity, baseline ALT, and csDMARDs as the explanatory variables, only baseline ALT level [hazard ratio 1.56 per 1 SD increase, 95% confidence interval (CI) 1.30–1.88, $p < 0.001$] was associated with incident ALT-elevations. Survival according to normalized baseline ALT is shown in Figure, where normalized ALT value of 1.0 refers to the upper limit of reference range (women 35 U/l, men 50 U/l).

Table. Multivariable Cox proportional hazards model including the results of the first follow-up laboratory test. Only values before occurrence of primary endpoint were used (n=843).

Characteristic	Hazard ratio (95% CI)	P Value
Age (per year)	1.00 (0.98-1.02)	0.78
Sex (male)	0.50 (0.21-1.15)	0.10
Seronegativity	0.88 (0.44-1.75)	0.71
Baseline ALT*	1.72 (1.32-2.25)	<0.001
ALT / t (per 1 SD increase / 30 days) §	1.33 (1.17-1.52)	<0.001
Methotrexate	0.58 (0.22-1.52)	0.27
Sulfasalazine	0.95 (0.38-2.35)	0.91
Azathioprine	2.30 (0.48-11.13)	0.30
Leflunomide	1.08 (0.23-5.16)	0.92

*Normalized ALT according to sex-specific reference range; §Rate of change from baseline to 1st follow-up test

Conclusion: Most incident ALT elevations can be predicted before the first csDMARD dose. Patients with elevated ALT at baseline or a rising trend at first follow-up are at high risk for liver toxicity and benefit from frequent testing.

References:

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THU0562

ECONOMIC IMPACT ASSOCIATED WITH COMPLICATIONS OF WOMEN IN REPRODUCTIVE AGE LIVING WITH INFLAMMATORY IMMUNE-MEDIATED DISEASES (PSO, PSA, RA, AXSPA) IN SPAIN

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Background: Cost of the complications that may appear during reproductive age in women living with inflammatory immune-mediated diseases have scarcely been studied.

Objectives: To obtain an expert consensus in the use of resources associated to complications of women in reproductive age living with immune-mediated diseases: psoriasis (PSO), psoriatic arthritis (PsA), rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) and estimate an economic impact.

Methods: A cost-analysis was developed to estimate the impact associated with the complications of women of reproductive age with PSO, PsA, RA and axSpA. The analysis considered the complications during fertility and conception (pre-conception consultation and assisted reproduction), in pregnancy (miscarriage in the first trimester, late abortion in the second trimester, preeclampsia, delayed or restricted intrauterine growth and threat of premature delivery) and in the postpartum (admissions in neonatology of premature infants).

An online questionnaire was designed for the validation of the inputs used in the cost-analysis. Subsequently, the questionnaire was sent to a multidisciplinary panel composed of, rheumatologist, gynecologists, neonatologists and dermatologist. A consensus meeting was carried out to validate and agree the parameters used in the analysis.

Unitary cost for resources (€,2019) were obtained from national local databases. The perspective of analysis was the National Healthcare System and the time horizon was one year.

Results: During fertility and conception, an annual cost per patient of € 229 was estimated for a preconception consultation in a patient with PSO, of € 3,642 for a preconception consultation in patients with PsA, RA and axSpA and € 4,339 for assisted reproduction.

Women with complications in pregnancy had an annual cost per patient of € 1,214 for a miscarriage in the first trimester, € 4,419 for a late abortion in the second trimester, € 11,251 for preeclampsia € 3,183 for delayed or restricted intrauterine growth and € 12,122 for the threat of premature delivery.

In the postpartum complications, an annual cost per patient of € 120,364, € 44,709 and € 5,507 were estimated associated with admissions in neonatology of premature infants of <28 weeks, from 28 to 32 weeks and from 33 to 37 weeks, respectively.

Conclusion: This modeling provides insight on the economic burden of complications associated with women in reproductive age for immune-mediated diseases (PSO, PsA, RA, axSpA). Individualization of treatment, additional and close monitoring may reduce the risk and burden of these complications.

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THU0563

IMMUNOGENICITY AND SAFETY OF 23-VALENT PNEUMOCOCCAL VACCINE IN PATIENTS WITH ANKYLOSING SPONDYLITIS (PRELIMINARY RESULTS).

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Background: For the treatment of patients with ankylosing spondylitis (AS), biological drugs are widely used, which can effectively control the activity of the disease and radically change the prognosis. However, the use of these drugs is associated with an increasing risk of infections, some of which can probably be prevented by vaccination.

Objectives: The aim of the study was to evaluate the immunogenicity and safety of the 23-valent pneumococcal vaccine (PPV-23) in patients with AS.

Methods: The study included 18 patients with AS: 14 men, 4 women, age 38.7±11.5 years, duration of the disease 16.2±10.8 years. 5 patients had a history of more than 2 episodes of lower respiratory tract infections (pneumonia, bronchitis). At the time of inclusion in the study in 89% of patients, activity of

diseases was assessed as high (median BASDAI was 5.1 [4; 6.2]). All patients received non-steroidal anti-inflammatory drugs, 6 patients - sulfasalazine, 4 - methotrexate, 1 - glucocorticoids, 1 - etanercept. PPV-23 was administered in an amount of 1 dose (0.5 ml) subcutaneously against the background of therapy. In 14 patients vaccination was performed before the appointment of secukinumab; 2 of them continued to take methotrexate, 3 - sulfasalazine. The level of antibodies to pneumococcal capsular polysaccharide was determined using the EIA PCP IgG kit (TestLine Clinical Diagnostics s.r.o., Czech Republic) before vaccination, 1 and 3 months after vaccination. The duration of follow-up was 6.7±4.9 months.

Results: The dynamics of the concentration of antibodies to pneumococcal capsular polysaccharide is presented in the table.

Table. Concentration of pneumococcal antibodies in patients with AS, U/ml, Me [25; 75 percentile]

1 visit (initial)	2 visit (after 1 month)	3 visit (after 1 month)
78.2 [35.2; 246.3]	246.7 [148.6; 266.1]*	261.1 [214.1; 273.4]**

*p=0.04 **p=0.008

After 1 and 3 months after vaccination, the concentration of antibodies to pneumococcal capsular polysaccharide was significantly higher than the baseline values. None of the patients had lower respiratory tract infections. There was no exacerbation of disease. 83% of patients did not have any adverse effects of vaccination. Reactions at the injection site (pain, swelling and hyperemia of the skin up to 2 cm in diameter), resolved independently after 3-5 days, were noted in 2 patients. One patient registered a severe local reaction (infiltration and hyperemia of the skin up to 8 cm in diameter, pain in the arm), accompanied by low-grade fever for 2 days, which required the appointment of antihistamine drugs.

Conclusion: Preliminary results indicate satisfactory immunogenicity and safety of the PPV-23 in patients with AS. Further research is needed to better assess the immunogenicity, efficacy and safety of the vaccine.

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THU0564

PARTICIPANT ENGAGEMENT IN AN ARTHRITISPOWER REAL-WORLD STUDY TO CAPTURE SMARTWATCH AND PATIENT-REPORTED OUTCOME DATA AMONG RHEUMATOID ARTHRITIS PATIENTS

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Background: Clear characterization of how different types of patient-generated data reflect patient experience is needed to guide integration of electronic patient-reported outcome (ePRO) measures and biometrics in generating real-world evidence (RWE) related to rheumatoid arthritis (RA).

Objectives: To characterize the level of participant (pt) engagement/adherence and data completeness in an ongoing study of 250 RA pts enrolled in the Digital Tracking of Arthritis Longitudinally (DIGITAL) study¹ of the ArthritisPower real-world registry.

Methods: ArthritisPower pts with RA were invited to join a digital RWE study with 14-day lead-in and 12-week main study period. In the lead-in, pts were required to electronically complete: a) two daily single-item Pain and Fatigue numeric rating scales and b) longer weekly sets of ePROs. Successful completers of the lead-in were mailed a smartwatch (Fitbit Versa) and study materials. The smartwatch collected activity, heart rate, and sleep duration/quality biosensor data; a study-specific customization of the ArthritisPower mobile application collected ePROs. The main study period included automated and manual reminders/prompts about completing ePROs, wearing the smartwatch and regularly syncing it. Study coordinators monitored pt data and contacted pts via email, text and/or phone to resolve adherence issues during the conduct of the study based on pre-determined rules triggering pt contact. Rules were based chiefly on consecutive spans of missing data. Pts were considered adherent in giving complete data for each week if providing (1) daily ePROs for ≥5 of 7 days/week, (2) weekly ePROs and (3) ≥80% of synced activity data for ≥5 of 7 days/week. Composite adherence for the first month of the main study period required meeting >70% weekly adherence parameters during the first 30 days, ie completing

daily ePROs for ≥5 of 7 days/week, weekly ePROs ≥3 of 4 weeks and ≥80% of synced activity data for ≥5 of 7 days/week.

Results: As of December 2019, 170 ArthritisPower members enrolled and completed at least 30 days of the main study period; 92.9% female with mean (SD) age 52.5 (10.7) and 10.5 (10.4) years since diagnosis. The overall conversion rate from initial interest to successful completion of the lead-in period was 49.0%. Pts who advanced to the main study were significantly more likely than those who did not to be currently employed (52.9% vs. 41.8%, p=0.038) and be on biologic DMARD monotherapy (64.7% vs. 47.5%, p=0.001). Overall, daily ePRO data had the lowest adherence with 70.0% of pts providing >70% of the requested data consistently across the first 30 days of the main study period (Figure 1). Composite adherence was met by 66.5% of pts. The most common time of day to provide ePRO data was morning, in the hours around scheduled app and email notifications at 10 a.m. in pt's local time zone. Activity data had the highest adherence and persistence, with 92.9% of pts providing 80% or more of activity data for each 24-hour period in the first 30 days (Figures 1 & 2). Observed weekly adherence did not decline over time. Of 5100 possible person days in the study at day 30, we observed 643 days (91.0% of actual to maximum possible total patient days) where activity data was provided for at least 80% of the 24-hour period.

Conclusion: RWE studies involving passive data collection in RA require pt-centric implementation and design to minimize pt burden, promote longitudinal engagement and maximize adherence. Passive data capture via activity trackers such as smartwatches, along with regular contact such as automated reminders, may facilitate greater pt adherence in providing longitudinal data for clinical trials.

References:

[1] Nowell WB, et al. JMIR Res Protoc. 2019;8(9):e14665.

Figure 1. Completeness of Data in Lead-in and Main Study Period, Month 1 (N=170)

Figure 2. Participant Persistence in Providing Data by Data Type, Month 1* (N=170)

*Main study period only

- ePRO 1d: Days until 1st day without ePRO data (number of days until the patient has their first day without daily or weekly ePRO data)
- ePRO 7d: Days until 7 consecutive days without ePRO data (first occurrence of 7 days with no PRO)
- Activity 1d: Days until 1st day without activity data
- Activity 7d: Days until 7 consecutive days without activity data
- Sleep 1d: Days until 1st day without sleep data
- Sleep 7d: Days until 7 consecutive days without sleep data

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