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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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 (preconception 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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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