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OP0039

RISK OF ARRHYTHMIA AMONG NEW USERS OF HYDROXYCHLOROQUINE: A LONGITUDINAL POPULATION-BASED COHORT STUDY ON NEWLY DIAGNOSED RHEUMATOID ARTHRITIS AND SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS

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Background: Previous findings on hydroxychloroquine (HCQ) use and the risk of arrhythmia are contradictory and low-level evidence-based results. Additional research is required to evaluate the safety profile of HCQ to arrhythmia in managing rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).

Objectives: To assess the association between HCQ initiation and risk of incident arrhythmia among newly diagnosed RA and SLE patients.

Methods: All patients with incident RA or SLE and no arrhythmic events or anti-arrhythmic medications and no HCQ use prior to disease index date in British Columbia, Canada, between January 1997 and March 2015 were identified using administrative databases. HCQ initiator and HCQ non-initiator groups were identified and matched 1:1 by propensity scores using baseline confounders on demographics including presence of RA or SLE disease and duration of disease prior to the index date of HCQ initiators or non-initiators, comorbidities, other medications, and healthcare utilization. Matching was done within the same calendar year to account for a potential secular trend in HCQ use and risk of arrhythmia. Outcomes were any new arrhythmias, atrial fibrillation, abnormal electrocardiogram including prolonged QT syndrome and conduction disorder, and other unspecified arrhythmias during follow-up. We used Cox proportional hazard models with death as a competing event to assess the association of HCQ initiation and the outcomes.

Results: We identified 11,518 HCQ initiators (10,655 RA and 863 SLE patients, mean \pm SD age 55.9 \pm 15.1 years, 76.1% female) and 11,518 HCQ non-initiators (10,639 RA and 879 SLE patients, mean \pm SD age 56.0 \pm 16.2 years, 76.4% female) after 1:1 propensity score matching. Over the mean follow-up of eight years, there were 1,610 and 1,646 incident arrhythmias in the HCQ initiator and non-initiator groups, respectively. The crude incidence rates of arrhythmia were 17.5, and 18.1 per 1,000 person-years, respectively. Cumulative risk of incident arrhythmia remained similar for both groups. (Figure 1). Adjusted hazard ratio (aHR) of incident arrhythmia from the Cox proportional hazard model for HCQ initiators was 0.99 (95% CI: 0.92-1.06) compared to non-initiators (Table 1). The corresponding aHRs for HCQ initiators in subtypes of arrhythmia – atrial fibrillation, abnormal electrocardiogram, and other unspecified arrhythmias were 0.95 (95% CI: 0.84-1.06), 1.04 (95% CI: 0.87-1.26), and 0.96 (95% CI: 0.86-1.08), respectively.

Table 1. Incident arrhythmias of any type among RA and SLE patients initiating HCQ prescription compared with HCQ non-initiators

	HCQ initiator	HCQ non-initiator
Participants (number)	11,518	11,518
Mean follow-up (years)	8.00	7.89
Events (number)	1,610	1,646
Crude incidence rate per 1000 person-years	17.48	18.12
Unadjusted HR (95% CI)	0.98 (0.91-1.05)	1.00 (reference)
Adjusted# HR (95% CI)	0.99 (0.92-1.06)	1.00 (reference)

Abbreviations: **HCQ**, hydroxychloroquine; **HR**, hazard ratio. #The multivariable Cox proportional hazard model was adjusted for baseline confounders on demographics, comorbidities, medications, and healthcare utilization.

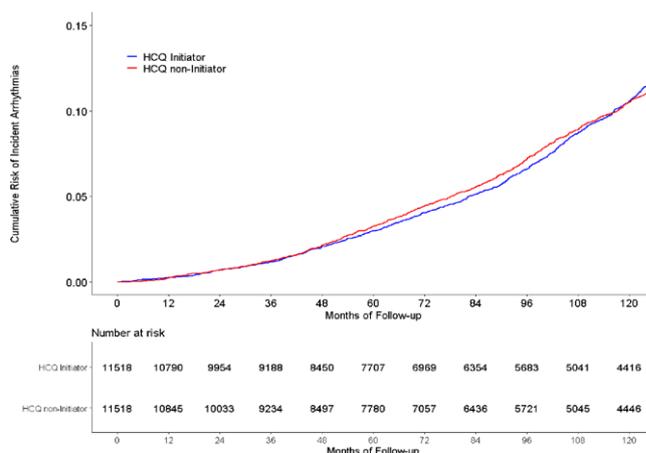


Figure 1. Cumulative risk of incident arrhythmias for HCQ initiators and non-initiators over the follow-up time.

Conclusion: There is no increased risk of any type of arrhythmia among new users of HCQ in RA and SLE patients. We believe the results of this large cohort study will add to the confidence with which HCQ can be used in RA and SLE management.

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In dialogue with the expert: axSpA and Sjögren's syndrome

OP0040-PARE

THE WEBINAR SERIES FOR THE PATIENTS "PREGNANCY AFTER DIAGNOSING ANKYLOSIS SPONDYLITIS"

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Background: Having been diagnosed with ankylosis spondylitis (AS), 68,2% of females in Russia reconsider their plans for pregnancy, with 13% giving up motherhood altogether out of fear for their own and their child's potential health problems. However, most females allow pregnancy while experiencing emotional discomfort and anxiety¹.

Objectives: To shed more light on the mutual influence of AS and pregnancy, AS pregnancy outcomes, clinical course of AS as well as medication options during AS and lactation.

Methods: From 03/2021 to 12/2021 an on-line series of eight webinars was conducted together with the patients' Russian ankylosing spondylitis association. Each webinar included lectures of one or two rheumatologists and an obstetrician; furthermore, the series included the presentations of a physical therapy instructor (with the demonstration of exercises) and of a breast-feeding specialist. After the lecture each speaker answered the audience's questions. Topics of rheumatologists' lectures were "AS and pregnancy: problem introduction"; "What do we know about AS genetics"; "Features of pregnancy planning" (included therapy issues for men with AS who are planning to father a child), "Rheumatologist prenatal and postnatal care" (included the analysis of AS clinical manifestations such as potential changes in back pain type); "Contemporary approaches to AS pregnancy treatment." A brochure for the patients with the main provisions of the lectures had been developed in support of the series.

Results: Webinars scored 703±192 views (by 29.01.2022). According to the questionnaire survey of the audience, 43,8% first knew that it was necessary to plan AS pregnancy minimum 3-6 months before conception; 25% – that conception is optimal during remission or low AS activity; 31,3% – that medical therapy can be continued during pregnancy; 18,8% – that it is necessary to inform the obstetrician about AS diagnosis and therapy received. 80% of the participants are fully satisfied with the information provided by the web series; 13,3% – reported not to have received enough information.

Conclusion: The interest in webinars shows that the choice of the form and the information provided was successful. The content of the series can be used to develop FAQ-section on the patient's website "Ankylosing Spondylitis Association". In 2022, lectures will continue taking into account patients' feedback.

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OP0041-PARE SJÖGREN EUROPE: REVIEW OF ITS FIRST THREE YEARS OF ACTIVITY

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Background: Sjögren Europe was founded on 23 February 2019 by several European patient organisations representing Sjögren's patient to help to address the lack of visibility, attention, and solutions for Sjögren's.

Objectives: To show the first achievements and contributions of the federation.

Methods: Sjögren Europe's purpose is to promote the advancement of knowledge, research, information, treatment, and care, to foster patient involvement and participation in research and any other relevant area, to increase awareness, identify the different unmet needs and articulate patient voices throughout Europe.

Results: Finding one's bearings and the right rhythm during the first years of an organisation's life is a challenge in itself. The Covid-19 pandemic has made this process even more difficult. Our first goal was to organise a first face-to-face European patient conference. This meeting had to be postponed. However, we were able to adapt and develop a range of activities.

We organised a series of informative webinars on different topics by leading European experts for patients and others interested in the subject. We have organised various awareness campaigns such as a campaign for Sjögren Awareness Month in 2021 for which we have created 2 awareness videos and published several testimonials. We also created a 3-axis campaign about fatigue for World Sjögren's Day 2021 which won the Best Practice Award at the 2021 PARE Conference, and during which we shared the patients' perspective on fatigue in publications in 13 languages on social media. We published a booklet about fatigue developed by a specialist and produced 3 informative leaflets for patients. We also subtitled 2 videos made by one of our members in 10 European languages to disseminate quality information that many patients miss. We have been involved in various research projects, working groups and patient panels and have been able to bring the patient perspective to various stakeholders on many occasions.

Conclusion: Despite the limited contacts, we were able to create strong links and rich discussions that stimulated our creativity. Sjögren Europe has become a privileged partner, recognised, and appreciated by the various stakeholders. Patients with Sjögren's are better represented at the supranational level. It is our members, the national patient organisations, who by their trust give us our legitimacy. In return, Sjögren Europe has been able to inject a new energy and dynamism that can be felt at the different national levels and that opens up many perspectives and opportunities. We have been able to strengthen our presence and visibility with patients on social networks, where our audience is constantly growing, as well as in the rheumatology field with researchers, clinicians, industry, and associations such as EULAR. The resumption of face-to-face contacts is eagerly awaited to consolidate the links already created and to feed the richness, relevance, originality and diversity of our discussions and activities.

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Infection-related and other orphan rheumatic disorders

OP0042

LONG-TERM EFFICACY AND SAFETY OF CANAKINUMAB IN PATIENTS WITH FAMILIAL MEDITERRANEAN FEVER (FMF) - INTERIM ANALYSIS OF THE RELIANCE REGISTRY

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Background: Familial Mediterranean Fever (FMF) is a chronic disease characterized by recurrent attacks of fever as well as serositis and bears the risk of serious complications (e. g. amyloidosis). Treatment of FMF according to EULAR aims to control acute attacks and subclinical inflammation as well as to improve patient's quality of life¹. Clinical data indicate that the inhibition of interleukin-1 β with canakinumab (CAN) is effective in controlling and preventing flares in FMF patients².

Objectives: The present study explores the long-term efficacy and safety of canakinumab in routine clinical practice conditions in pediatric (age ≥ 2 years) and adult FMF patients.

Methods: RELIANCE is a prospective, non-interventional, multi-center, observational study based in Germany with a 3-year follow-up period. Patients with clinically confirmed FMF diagnosis who routinely receive canakinumab are enrolled in order to evaluate effectiveness and safety of canakinumab. Disease activity and remission by physicians' assessment, disease activity, fatigue and impact on social life by patients' assessment, inflammatory markers and AIDAI (Auto-Inflammatory Diseases Activity Index) score were recorded at baseline and assessed at 6-monthly intervals within the 3-year observation period of the study.

Results: This interim analysis of FMF patients (N=74) enrolled by December 2021 includes baseline as well as 6- to 24-month data. Mean age in this cohort was 25 years (2–61 years) and the proportion of female patients was 51 % (N=38). At baseline, median duration of prior CAN treatment was 1.0 years (0–6 years).

At month 24, physician ratings report around 63% of patients in disease remission and patient-reported disease activity (mean PPA) decreased from moderate (3.0) to low (2.6) during the observation period. Other disease activity parameters also decreased (Table 1). A total of 18 serious adverse events were reported, of which 2 (1 case of tonsillectomy and 1 case of tachycardia) were classified as drug-related.