LO-024 ASSOCIATION BETWEEN SEVERE NON-ADHERENCE TO HYDROXYCHLOROQUINE AND SLE FLARES, DAMAGE, AND MORTALITY IN 660 PATIENTS FROM THE SLICC INCEPTION COHORT

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Background Hydroxychloroquine is one of the major treatment of SLE, but its effectiveness is impaired by non-adherence, reported to range from 3% to 85% in SLE patients. Our objective was to assess the associations of severe non-adherence to HCQ, objectively assessed by HCQ serum levels, and risks of SLE flares, damage, and mortality over 5 years of follow-up.

Methods The SLICC Inception Cohort is a multicenter initiative (33 centers; 11 countries). Serum of patients taking HCQ for at least 3 months, sampled at enrolment or during the first-year follow-up visit, were analyzed. Severe non-adherence was defined by a serum HCQ level <106 ng/ml or <53 ng/ml, for daily HCQ doses of 400 or 200 mg/d, respectively. Association with the risk of a flare (defined as a SLEDAI-2K increase ≥4 points, initiation of prednisone or immunosuppressive drugs, or new renal involvement) was studied with logistic regression, and association with damage (first SLICC/ACR Damage Index (SDI) increase ≥1 point) and mortality were studied with separate Cox proportional hazard models.

Results Of 1849 cohort subjects, 660 patients (88% women) were included. Median [interquartile range] serum HCQ was 388 ng/ml (244–566); 48 patients (7.3%) had severe HCQ non-adherence. No factors were clearly associated with severe non-adherence. Severe non-adherence was independently associated with flare (OR 3.38; 95% CI 1.80–6.42) and of an increase in the SDI within each of the first 3 years (HR 1.92 at 3 years; 95% CI 1.05–3.50). Eleven patients died within 5 years, including 3 with severe non-adherence (HR 5.41; 95% CI 1.43–20.39).

Conclusions Severe non-adherence was independently associated with the risk of an SLE flare in the following year, with early damage and 5-year mortality. Our results suggest the benefits of testing of detecting severe non-adherence and dedicating more resources and more time to these patients, to improve their long-term prognosis.

Concurrent session 7: pregnancy and reproductive issues

LO-025 INCREASING PRE-ECLAMPSIA KNOWLEDGE AND HIGHER PREVALENCE OF ASPIRIN USE IN SLE WITH A SPECIFIC EDUCATIONAL TOOL: INTERIM ANALYSES OF A RANDOMIZED CONTROLLED TRIAL

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Background Pregnant SLE women are at high risk of pre-eclampsia. Aspirin reduces its risk but is used only in a minority of SLE pregnancies. This randomized controlled trial evaluated a specifically-designed educational tool on pre-eclampsia knowledge, aspirin use and adherence in SLE pregnancies. We present interim results.

Methods We recruited pregnant SLE women up to 16 gestational weeks at 5 Canadian SLICC centres. Participants were randomly assigned to the educational tool (intervention) or standard of care (control). At every pregnancy visit, participants completed pre-eclampsia questionnaire, aspirin survey, and modified Adherence to Refills and Medications Scale (ARMS). We performed Student's t-test and univariate linear regression to assess pre-eclampsia knowledge, and estimated 95% CI for difference in proportion of aspirin users using the Wilson procedure. We evaluated mean ARMS score difference with Student's t-test and Mann-Whitney U test.

Results Thirty-eight women were included, with 20 exposed to the intervention. Baseline characteristics were well-balanced. The difference in mean pre-eclampsia knowledge scores between 1st and 2nd trimester visits in the intervention group was 5.0 points (95% CI 1.4, 8.6) and 1.1 points (95% CI -3.1, 5.4) in the control group when all women were included regardless of fetal loss. The mean difference in scores for those receiving the educational tool was 4.1 points higher (95% CI 0.4, 7.9) than those receiving standard of care. There was a trend of higher aspirin use in the intervention group. Aspirin adherence was high regardless of intervention status.

Conclusions Midway into the trial, pre-eclampsia knowledge improved from 1st to 2nd trimester visits in pregnant SLE women who received the tool compared to those who did not. There was a trend of higher aspirin use in women receiving the educational tool. The trial is well-poised to provide a new evidence-based approach to improve pre-eclampsia knowledge and potentially optimize aspirin use and pregnancy outcomes.

LO-026 HYDROXYCHLOROQUINE USE IN PREGNANT WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND MAJOR CONGENITAL MALFORMATIONS IN THE OFFSPRING

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Background Some studies have reported an increased risk of major congenital malformations (MCM) associated with hydroxychloroquine (HCQ), but others find no increased risk. We aim to assess the risk of MCM associated with 1st-trimester HCQ exposure in the offspring of women with lupus.

Methods We conducted a population-based cohort study of pregnancies (2006–2020) with a singleton birth among women with prevalent lupus in Sweden. Prevalent lupus was defined as having ≥ two ICD-coded visits in the National Patient Register before pregnancy, with ≥ one with a lupus specialist. HCQ exposure was defined as filling ≥ one HCQ prescription during the 1st trimester (Prescribed Drug Register). MCM was assessed at birth by any ICD code in the Swedish Medical Birth Register. Inverse probability of treatment weighting (IPTW) was applied to adjust for confounding. Risk ratios and 95% confidence intervals (RR 95%CI) were estimated using modified Poisson regression models with robust variance estimation.

Results We included 407 exposed births and 520 unexposed births. The risks of MCM in the full cohort, the exposed, and the unexposed were 2.3%, 2.7%, and 1.9%, respectively (unadjusted RR 1.42, 95%CI 0.60–3.28). The IPTW-adjusted population achieved a good balance across patient characteristics. The IPTW-adjusted RR was 1.59 (0.67–3.75). The adjusted risk difference was 0.01 (-0.01–0.03). When the exposure was defined as having ≥ one HCQ dispensation from three months preconception to the end of the 1st trimester, the IPTW-adjusted RR was 1.56 (0.69–3.54).

Conclusions Our findings show an increased, but not statistically significant, risk of MCM at birth among births born to women with lupus exposed to HCQ during the 1st trimester compared to those without HCQ exposure. Future studies are warranted and should utilize a longer follow-up for MCM ascertainment (i.e., within one year of birth). For managing lupus during pregnancy, the benefits of HCQ may still outweigh the risks.

LO-027 COVID-19 VACCINE SAFETY DURING PREGNANCY IN WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background While COVID-19 vaccination has been shown to be safe in patients with systemic lupus erythematosus (SLE), data on vaccine-associated adverse events (AEs) during the antenatal and lactation period are scarce, justifying the present investigation.

Methods A total of 9201 complete responses were extracted from the COVID-19 Vaccination in Autoimmune Diseases (COVAD) database, a global e-survey involving 157 collaborators from 106 countries. Among respondents, 6787 (73.8%) were women. We identified 70 (1.1%) women who were exposed to at least one COVID-19 vaccine dose during pregnancy, among those 11 with SLE.

Results The age of patients ranged from 28 to 39 years; 5/11 women were of Asian origin. None of these patients reported major vaccine AEs, change in the status of their autoimmune disease, hospitalisation, or special treatment requirement. Six women experienced minor vaccine AEs; two of them had active disease prior to vaccination. Four patients reported COVID-19 infection; two of them while they were pregnant and post-vaccination and two prior to pregnancy and vaccination. All four patients experienced symptoms of their disease, but no overt SLE flare was reported. All patients reported their general health to be good/excellent. Importantly, no adverse pregnancy outcomes were reported. No post-vaccination thrombotic events were recorded. Although minor AEs were common, they did not impair daily functioning, and the symptoms resolved in all patients after a median of 3 (IQR: 2.5–5.0) days.