Background: Vaccinations comprise a part of the antenatal care of pregnant women, including patients with systemic lupus erythematosus (SLE) who are at increased risk of adverse pregnancy outcomes (APOs). While COVID-19 vaccination has been shown to be safe in patients with SLE, data on vaccine-associated adverse events (AEs) during the antenatal and lactation period are scarce or lacking.

Objectives: To investigate the association between COVID-19 vaccination and AEs in pregnant SLE patients.

Methods: A total of 9201 complete responses were extracted on June 21st, 2022 from the COVID-19 Vaccination in Autoimmune Diseases (COVAD) 2 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. Delayed onset (>7 days) vaccine-related AEs were extracted and triangulated with disease activity, treatment changes due to flare after vaccination, and COVID-19 infections in vaccinated pregnant women with SLE. Additionally, information on health-related quality of life and physical function was recorded using PROMIS at the time of survey completion.

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, including four patients with self-reported active SLE prior to the vaccination. None of them reported any change in the status of their autoimmune disease, and no hospitalisation or special treatment was recorded. Six women experienced minor vaccine AEs; two of them had active disease prior to vaccination. Four patients reported COVID-19 infection; two of them 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. At the time of survey completion, all patients reported their general health as being good to excellent in all aspects evaluated. Importantly, no APOs were reported. None of the patients reported thrombotic events post-vaccination, which provides some reassurance regarding COVID-19 vaccination in a patient population with a high risk for cardiovascular comorbidity and thrombosis, especially in the presence of antiphospholipid antibodies or in patients diagnosed with the antiphospholipid syndrome, a considerable portion within SLE populations. Moreover, it was reassuring to note an absence of association between experienced vaccine AEs and active disease prior to vaccination. 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.

Conclusion: Our report adds relevant evidence concerning the sensitive issue of COVID-19 vaccine AEs and flares in SLE patients during the antenatal and lactation period. Despite the small sample size, the findings provide some reassurance and can contribute to informed decisions regarding vaccination in patients with SLE and high-risk pregnancies due to their background autoimmune disease. Based on the present data, the risk/benefit ratio of COVID-19 vaccination appears favourable, with vaccines both providing passive immunisation to the fetus and active immunisation to the mother with no signals of exacerbation of the mother's autoimmune disease.

Acknowledgements: The authors thank all survey respondents, as well as patient associations and all members of the COVAD study group for their invaluable role in the data collection.

Disclosure of Interests: Nefeli Giannopoulou: None declared, Latika Gupta: None declared, Laura Andreoli: None declared, Dario Lini: None declared, Elena Nikphorou: None declared, Rohit Aggarwal Grant/research support from: IQ V has a consultancy relationship with and/or has received research funding from Bristol Myers-Squibb, Pfizer, Genentech, Octapharma, CSL Behring, Mallinckrodt, AstraZeneca, Boehringer Ingelviant, Roivant, Merck, Galapagos, Actigraph, Scipher, Horizon Therapeutics, Teva, Beigene, ANI Pharmaceuticals, Biogen, Nuvig, Capella Bioscience, and CibaGenBio, Vikas Agarwal: None declared, Ioannis Parodi Grant/research support from: I.P has received research funding and/or honoraria from Amgen, AstraZeneca, Aurinia Pharmaceuticals, Eli Lilly and Company, Gilead Sciences, GlaxoSmithKline, Janssen Pharmaceuticals, Novartis, and F. Hoffmann-La Roche AG.

DOI: 10.1136/annrheumdis-2023-eular.5611

AB0592 COMPARATIVE CARDIOVASCULAR RISK IN PATIENTS WITH OLDER-ONSET SYSTEMIC LUPUS ERYTHEMATOSUS: A NATIONWIDE RETROSPECTIVE COHORT STUDY IN KOREA

Keywords: Cardiovascular disease, Systemic lupus erythematosus

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Background: Patients with systemic lupus erythematosus (SLE) have increased mortality related to cardiovascular disease (CVD) and the age is one of important risk factors for the development of CVDs. However, the comparative risk of CVDs in patients with older onset SLE has not been well studied.

Objectives: This study aims to compare the CVD risk in patients with SLE occurred after the age of 40 compared to those with DM.

Methods: Incident SLE patients aged over 40 years and age-sex matched (1:4:4) controls with DM or general population were identified from the nationwide claims database in Korea between 2008 and 2018. We defined CVD risk as ischemic heart disease, stroke, and cardiac death. The incidence rates (IR) and incidence rate ratio (IRR), and adjusted hazard ratio (HR) of CVDs were calculated using generalized estimating equation models.

Results: We identified 4,272 SLE, 17,003 DM, and 17,088 general population patients aged over 40 years. Their mean age was 53.1 (+9.7) and 81.7% of them were female. The IR per 1,000 person-years (PYs) of CVDs for SLE, DM, and general population were 16.8, 11.7, and 5.7, respectively. Compared to general population, patients with SLE (IRR 3.27, 95% CI 2.78-3.85) and DM (IRR 2.77, 95% CI 2.02-3.56) showed higher CVD risk compared to general population. Increased risk of CVDs in SLE patients was highest in their forties (IRR 4.13, 95% CI 3.06, 5.59). After adjusting confounders, the CVD risk of SLE (HR 1.99, 95% CI 1.66-2.38) was higher than DM (HR 1.39, 95% CI 1.22-1.58) patients.

Conclusion: Older onset SLE patients had increased CVD risk compared to general population. Even after adjustment for confounders, SLE patients showed higher CVD risk than DM patients in Korea.

Acknowledgements: This research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HI19C1202).

Disclosure of Interests: None Declared.

DOI: 10.1136/annrheumdis-2023-eular.5912