placebo group, 9 patients [2.5%]). During the study, 8 anifrolumab-treated patients (2.2%) and 12 patients who received placebo (3.3%) used antidepressants; 1 (0.3%) and 4 (1.1%) patients, respectively, initiated antidepressant therapy during the study (1 in the placebo group stopped therapy). Suicidal ideation or behavior, as assessed by C-SSRS, during the study was reported in 5 anifrolumab-treated patients (1.4%) and 11 patients who received placebo (3.0%). Excluding patients taking antidepressants, suicidal ideation or behavior during the study was reported in 4 anifrolumab-treated patients (1.1%) and 9 patients who received placebo (2.5%) (figure 1).

Conclusions Patients with SLE treated with anifrolumab did not experience increased depression, suicidality, or need for antidepressants when compared with standard therapy, irrespective of baseline antidepressant use.

REFERENCES

Acknowledgements Writing assistance by Andrea Y. Angstad, PhD (Fishawack Health). This study was sponsored by AstraZeneca.

Submission deadline August 1, 2022 at 11:59 PM EST
Disclosures SM has received speaker fees from AstraZeneca; received consulting fees from AstraZeneca, Exagen Diagnostics, Inc, Cugene, GSK, Lilly, Lupus Foundation of America, and UCB Advisory Board; received grant support from HGS/GSK, AstraZenecea, and AbbVie. CL, IH, MS, and GA are employees of AstraZeneca. LZ, SW and RT are employees and shareholders of AstraZeneca.

Background People with SLE (and their doctors) are concerned about the risk of COVID-19 infection, yet some patients still harbor concerns regarding vaccination. The first mRNA SARS-CoV-2 vaccines were not studied in this population.1, 2 To address this knowledge gap, we evaluated the safety and side effects of mRNA SARS-CoV-2 vaccines in people with SLE.

Methods At a Canadian tertiary care centre, we studied SLE cohort patients who were followed with standardized annual assessments. From January 2021 to May 2022, 345 SLE patients consecutively seen for their annual research visit reported information on SARS-CoV-2 vaccinations. We performed descriptive data analysis on the type of vaccination received, side effects, ER visits, and hospitalizations.

Result The patients were mostly female (n=306, 88.7%) and Caucasian (n=209, 60.6%) and the average SLE duration was 19.7 years (SD 11.9). Most patients (n=298, 86.4%) had received at least one SARS-CoV-2 vaccination and 248 (71.9%) has received at least 2 doses. Specifically, 50 (14.5%) had received one dose, 150 (43.5%) had received 2 doses and 98 (28.4%) had received at least 3. Most (n=181, 60.7%) of initial doses were Pfizer, followed by Moderna (n=54, 18.1%), AstraZeneca (n=12, 4.0%) and Johnson & Johnson (n=1, 0.3%). (The remaining (n=50, 16.8%) were unknown type.) About two-thirds (n=159, 63.3%) of the second doses were Pfizer, and 49 (19.5%) were Moderna.

Among those receiving at least 1 vaccination dose, 34 of 128 patients who responded to the question reported symptoms post-vaccine (26.6%). The most common symptoms were fever and injection-related arm pain; both were reported at equal frequency (n=9, 7.0%). Other symptoms were fatigue and headache (n=6, 4.6% for both). There were 3 cases of myalgia and 2 cases of arthralgia. One patient reported hypertension after the first dose of vaccine which required a short 24h ER visit. The remaining did not specify their symptoms. No patients reported disease flare in the post vaccination period.

Amongst those who provided information about SARS-CoV-2 infection (n=243), 19.3% reported testing positive for SARS-CoV-2. Only one patient required hospitalization for SARS-CoV-2 infection and was vaccine naïve at the time. Conclusion SARS-CoV-2 mRNA vaccine side effects in this SLE population were reported in about a quarter of subjects but symptoms were mild, similar to reports in the general population. We did not detect any side effects requiring hospitalization. Since, in our cohort, the one subject requiring hospitalization was vaccine naïve, a benefit for SARS-CoV-2 vaccination in SLE seems evident.

REFERENCES