LUPUS SCIENCE & MEDICINE™

COVID-19 vaccination questionnaire in patients with systemic lupus erythematosus: an observational study

Rui-Juan Cheng , Yan-Hong Li, Zhi-Hui Liu, Aiping Zhou, Zhuhong Li, Ling Ma, Yi Liu

To cite: Cheng R-J, Li Y-H, Liu Z-H, *et al*. COVID-19 vaccination questionnaire in patients with systemic lupus erythematosus: an observational study. *Lupus Science & Medicine* 2023;**10**:e000975. doi:10.1136/lupus-2023-000975

R-JC, Y-HL and Z-HL are joint first authors.

Received 5 June 2023
Accepted 29 June 2023

Department of Rheumatology and Immunology, West China Hospital, Sichuan University, Chengdu, People's Republic of China

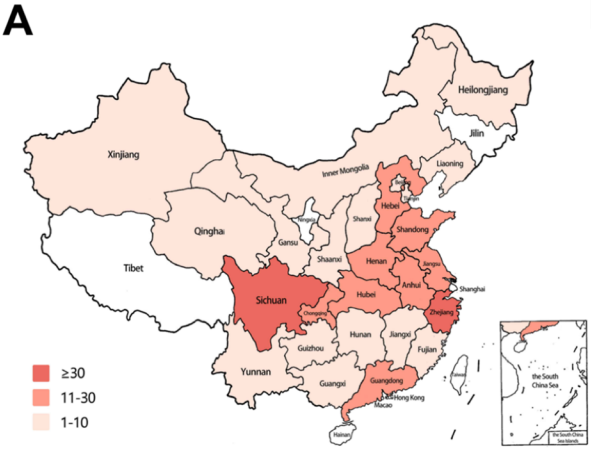
Correspondence to
Yi Liu; yiliu8999@wchscu.cn

As the COVID-19 epidemic has spread worldwide, two waves of peak COVID-19 infection have claimed many lives and left a legacy of sequelae. The widespread use of COVID-19 vaccination has significantly reduced the number of infections and serious illnesses. SLE is a typical autoimmune disease that occurs in women of childbearing age and affects various organs of the body with numerous antibodies in the blood. Patients with SLE are more susceptible to COVID-19 and are more likely to develop serious problems, but little is known about the indications for COVID-19 vaccination. Speculation and debate regarding whether patients with SLE can receive the COVID-19 vaccine and how disease-modifying anti-rheumatic drugs (DMARDs) affect the efficacy of the COVID-19 vaccine have never stopped. Here, we designed a questionnaire to perform an observational study.

The demographic information, medical histories, COVID-19 infection histories and prognosis of 459 patients with SLE were investigated (figure 1A,B). X^2 tests were used to analyse the data, and no clear association between vaccination and population characteristics and the basal medical history of the patients was found. Fifty-eight (24.5%) of the 237 vaccinated patients (140 fully vaccinated, 97 partially vaccinated) reported side effects, and the overall response was acceptable and broadly consistent with adverse effects in the general population.[1] In addition, 21 (8.9%) experienced local side effects such as redness, pain and induration at the injection site; 35 (14.8%) experienced systemic adverse effects such as transient fever, fatigue, urticaria and drowsiness; and 5 (2.1%) developed mild renal dysfunction such as elevated creatinine and proteinuria. In our survey, 42 (17.7%) reported SLE flare-up symptoms such as complement decline, hair loss, facial erythema, proteinuria, and joint swelling and pain, and 27 (11.4%) reported changes in laboratory indicators such as blood cell counts, liver and kidney function, complement and autoantibody profiles within 30 days of vaccination (figure 1C). There were no serious adverse reactions reported within 3 months of vaccination, and fluctuations in blood laboratory indicators were within a manageable range. It is interesting to note that adverse responses and changes in disease activity were comparable between individuals who received the entire vaccine plus booster injection and those who received only one dose. Consequently, this supports the viability and generalisability of the COVID-19 vaccine and booster injections for patients with SLE.

Regardless of a person's colour or gender, they are all generally susceptible to the coronavirus. The elderly, immunocompromised people and sicker people in particular are more likely to experience life-threatening complications after contracting COVID-19 and have greater fatality rates.[2] As a result, effectively containing the sources of infection and safeguarding those who are vulnerable are essential to halting the epidemic's progress. A total of 65.7% of the world's population will have received at least one dose of a COVID-19 vaccination as of 6 June 2022.[3] The current vaccination status of the population with SLE is therefore still very serious. Of the 222 (48.4%) patients with SLE who did not receive the vaccine, 42.23% were concerned about the vaccine's safety, 4.05% questioned its effectiveness against COVID-19 and 13.51% were unwilling to be vaccinated (figure 1D). Patients' belief in vaccination is greatly influenced by their doctors' recommendations, although the optimum vaccine for this particular population is still unknown. As a result, it is imperative to create SLE-related immunisation guidelines and move quickly to develop and popularise vaccines.

A



B

	Overall population	Vaccinated	Unvaccinated
No. of patients	459	237	222
Female	438	224	214
Age	36.45±9.93	36.2±9.29	36.71±10.58
Education	high school or less 202 junior college or university 240 Postgraduate degree 17	high school or less 103 junior college or university 124 postgraduate degree 10	high school or less 99 junior college or university 116 postgraduate degree 7
Stable Job	260/459	134/237	126/222
Companionship	334/459	172/237	162/222
Course of disease	10.1±6.88	10.11±6.48	10.17±7.29
Steroid use	279/459	130/237	149/222
DMARDs use	202/459	102/237	100/222
COVID-19 infection	Previously infected, recovered 5 Asymptomatic infected 3 Never been infected 451	Previously infected, recovered 5 Asymptomatic infected 2 Never been infected 230	Asymptomatic infected 1 Never been infected 221
Sequelae	Hyposmia 1	Hyposmia 1	None

C

	Vaccinated	Fully vaccinated	Partially vaccinated
No. of patients	237	140	97
Types of vaccines	inactivated vaccine 229 viral vector vaccine 1 recombinant protein vaccine 9 mRNA vaccine 1	inactivated vaccine 133 viral vector vaccine 1 recombinant protein vaccine 9	inactivated vaccine 96 mRNA vaccine 1
Adverse reactions within 3 months	None 179 Local adverse effects 21 Systemic adverse effects 35 Renal function decline 5	None 113 Local adverse effects 9 Systemic adverse effects 15 Renal function decline 3	None 66 Local adverse effects 12 Systemic adverse effects 20 Renal function decline 2
Blood test fluctuated within 3 months	27	13	14
Flare-up of SLE within 30 days	None 195 Complete blood count 1 Complement 6 Autoantibody 6 Hair loss 15 Facial erythema 5 New onset or exacerbation of proteinuria 7 pain and swelling in joints 7	None 124 Complete blood count 0 Complement 3 Autoantibody 3 Hair loss 10 Facial erythema 0 New onset or exacerbation of proteinuria 4 pain and swelling in joints 5	None 71 Complete blood count 1 Complement 3 Autoantibody 3 Hair loss 5 Facial erythema 5 New onset or exacerbation of proteinuria 3 pain and swelling in joints 2

D

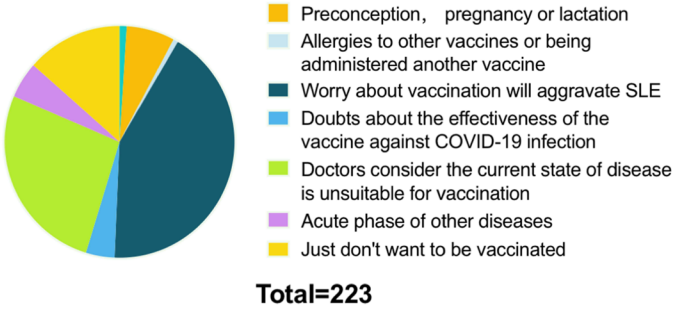


Figure 1 The results of a real-world COVID-19 vaccination questionnaire in patients with SLE. (A) Distribution of patients with SLE. (B) Demographic characteristics and basal medical history of patients with SLE. (C) Side effects or signs of SLE recurrence after vaccination. (D) The reasons why patients with SLE were not vaccinated. DMARDs, disease-modifying anti-rheumatic drugs.

A major obstacle to controlling high-intensity infectious illnesses, such as COVID-19, is vaccine refusal. Therefore, we asked patients what they wanted to know the most about the vaccine. The COVID-19 vaccine's efficacy and safety come first. Will getting vaccinated worsen or serve as a catalyst for relapse in patients with SLE who are in clinical remission? The timing of vaccinations is the second. How to time a vaccine in unique situations such as pregnant and lactating women or while dealing with concomitant conditions such as psychiatric symptoms, nephritis or pulmonary hypertension. There are many types of vaccines available, making the choice of COVID-19 vaccination more flexible and diverse. However, which vaccine is best suited for this particular population? How to answer these questions from patients is something we as physicians need to think about.

Our study started from clinical issues and initially explored the safety and feasibility of COVID-19 vaccination in patients with SLE. However, there are certain restrictions with our survey, such as the sample size and the lack of sufficient data in the DMARD categories. More long-term, large-sample randomised controlled trials on the safety and efficacy of the COVID-19 vaccine in patients with SLE and the management of the relevant side effects are urgently needed.

Acknowledgements We are grateful to the SLE community of Sichuan and Medical Doctor Weekly for their helpful advice and support.

Contributors R-JC and Y-HL conceived the idea and designed the questionnaire. AZ, ZL and LM collected data and followed up the patients. Z-HL analysed the data and drew the figures. R-JC wrote the manuscript. YL supervised the project.

Funding This work was supported by the National Natural Science Foundation of China (81771742), Sichuan University West China Hospital Science and Technology Achievement Transformation Fund Project (CGZH21005), and the Natural Science Foundation of Sichuan Province (project no. 2023NSFSC1752).

of its authorities. This map is provided without any warranty of any kind, either express or implied.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by the Ethics Committee on Biomedical Research, West China Hospital of Sichuan University (2021(368)). The Ethics Committee agrees to waive informed consent.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Rui-Juan Cheng http://orcid.org/0000-0002-1106-7599

REFERENCES

1 Kaplan RM, Milstein A. Influence of a COVID-19 vaccine's effectiveness and safety profile on vaccination acceptance. *Proc Natl Acad Sci U S A* 2021;118:e2021726118.
2 COVID-19 Forecasting Team. Variation in the COVID-19 infection-fatality ratio by age, time, and geography during the pre-vaccine era: a systematic analysis. *Lancet* 2022;399:1469–88.
3 Ritchie H, Mathieu E, Rodés-Guirao L, *et al*. Coronavirus pandemic (COVID-19. 2020. Available: https://ourworldindata.org/coronavirus