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COVID-19 vaccination of patients with chronic immune-mediated inflammatory disease

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Abstract

Objective This study aimed to analyze the safety and efficacy of COVID-19 vaccines among patients with chronic immune-mediated inflammatory disease (IMID) in China.

Methods Participants who were diagnosed with a chronic IMID were eligible for inclusion in this study. Age- and sex-matched healthy vaccinated individuals were set as the control group. All participants received two doses of the inactivated CoronaVac vaccine or three doses of the recombinant protein subunit vaccine ZF2001. Adverse events, IMID activity after vaccination, and the rate of COVID-19 in the two groups were compared.

Results There were 158 patients in the IMID group, with an average age of 40 ± 14 years old, and 98 female subjects. In the IMID group, 123 patients received the inactivated CoronaVac vaccine, and 35 patients received the recombinant protein subunit vaccine ZF2001. There were 153 individuals in the control group, including 122 who received the CoronaVac vaccine and 31 who received the recombinant protein subunit vaccine ZF2001. The frequency of vaccine-related adverse events in the IMID group was less than that in the control group, all of which were mild local effects, and no serious events occurred. Of note, no disease flares occurred in the IMID group. No participants in either group subsequently got COVID-19, so the incidence rate was 0% in both groups.

Conclusion COVID-19 vaccination was found to be safe for IMID subjects, any adverse events were mild, and vaccination did not increase the risk of disease activity. Meanwhile, vaccination could effectively reduce the incidence of COVID-19 in IMID patients. In the future, studies with a larger sample size and a longer duration are needed.

Keywords Immune-mediated inflammatory disease, COVID-19 vaccine, Safety, Efficacy

Background

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Since COVID-19 is easily transmissible, people can easily become infected. Following its outbreak in 2019, COVID-19 swept the world. According to data released by the World Health Organization in a platform committed to the development of digital health technologies, there have been more than 500 million confirmed cases worldwide, and more than 6 million people have died of the disease. Worse still, the constant mutation of the virus has brought greater challenges to the global control of the pandemic. To date, vaccination remains the most important way to control the pandemic. CoronaVac and recombinant subunit vaccines are the most commonly used vaccines in China. The efficacy of these vaccines for the prevention of symptomatic forms of COVID-19 is greater than 70%, and the adverse events

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are mild, with pain at the injection site being observed in phase III clinical data [1]. Patients with immune-mediated inflammatory disease (IMID) are at a high risk for COVID-19 due to immune dysregulation and chronic use of immunosuppressive drugs. At present, those with a IMID have been widely vaccinated with SARS-CoV-2 vaccines in China, but studies on the safety and efficacy of vaccination in IMID patients are lacking. Therefore, we performed a controlled trial that involved IMID patients and healthy adults (control group) who received two doses of CoronaVac or three doses of the recombinant protein subunit vaccine ZF2001 to evaluate the efficacy and safety of these vaccines in Chinese IMID patients.

Methods

This was a prospective cohort study. According to the Guidelines for COVID-19 Vaccination Techniques (Version 1) published in China [2] and the recommendations of the American College of Rheumatology for patients with rheumatic and musculoskeletal diseases on COVID-19 vaccines, patients with IMIDs in remission who met the following criteria were included in this study: age of 18–60 years old; no history of vaccine allergy; a diagnosed IMID, including systemic lupus erythematosus (SLE), primary Sjögren's syndrome (pSS), rheumatoid arthritis (RA), ankylosing spondylitis (AS), vasculitis, mixed connective tissue disease; stable disease for more than 3 months, with a disease activity score (e.g., SLEDAI, DAS28, ASDAS, and ESSDAI) indicating stable disease; and with no uncomfortable symptoms or active infections. After conducting vaccination education, vaccination was carried out if the participants consented. Age- and sex-matched healthy vaccinated individuals were set as the control group. Coronavac was inoculated in two doses on day 0 and day 56, respectively. The recombinant protein subunit vaccine ZF2001(Anhui Zhifei Longcom) was inoculated in three doses on day 0, day 42, and day 84, respectively. These regimens were approved by the Chinese government.

The primary objective of this study was to evaluate the safety and efficacy of these two vaccines at reducing the risk of COVID-19. None of the subjects in our study had COVID-19 before vaccination. We evaluated the vaccine efficacy by comparing the incidence of COVID-19 in the IMID group and the control group.

The participants were followed up for 90–180 days after vaccination. The first follow-up was conducted at seven days after vaccination, and all of the symptoms were recorded, including injection site reactions (pain, redness, and swelling) and systemic reactions. The participants were instructed on how to recognize signs and symptoms of COVID-19 and underwent SARS-CoV-2 nucleic acid detection tests if they had such symptoms. The participants were required to tell the investigators if symptoms occurred.

The disease activity scores on days 30 and 90 after vaccination were recorded (SLEDAI, ASDAS, DAS28 scores, etc.). Antirheumatic treatment continued during the vaccination period. The patients who received a venous injection of cyclophosphamide or rituximab resumed taking the drug at least four weeks after vaccination. The patients taking other drugs did not change the timing of their drug administration.

SPSS 26 software was used for data analysis. The t-test and chi-squared test were used for statistical analysis. The difference was considered statistically significant when $P<0.05$.

Results

A total of 160 patients were included in both groups. Two patients withdrew from the IMID group and seven participants withdrew from the control group because of their concerns about adverse events of the vaccine.

The average age of the patients in the IMID group was 40 ± 14 years old, and 98 individuals were female (Table 1). There were 77 individuals with SLE, 38 with RA, 33 with AS, 9 with pSS, and 1 with erythema nodosum. Among them, 80 patients received glucocorticoids at a dose of 2.5–15 mg per day; 38 received human tumor necrosis factor alpha inhibitors; 39 received methotrexate at a dose of 5–15 mg per week; 16 received mycophenolate mofetil; 7 received cyclosporine A; 69 received hydroxychloroquine; 5 received tocilizumab; and 16 received sulfasalazine (Table 2). With respect to vaccination, 123 participants were inoculated with the inactivated CoronaVac vaccine (Vero cells, Sinovac Life Sciences Co., Ltd.), and 35 participants received the recombinant protein subunit vaccine ZF2001.

There were 153 individuals in the healthy control group, including 96 females and 57 males, with an average age of 41.3 ± 16. 1 years old. A total of 122 participants were inoculated with the inactivated CoronaVac vaccine, and 31 participants received the recombinant protein subunit vaccine ZF2001.

The incidence of adverse events in the IMID group with Coronavac was less than that in the normal control group (19.5% vs. 50.8%, $P<0.05$), most of the adverse events were mild local reactions, and no serious events

Table 1 General characteristics of patients in the two groups

Demographics	IMID group ($n=158$)	Control group ($n=153$)	*P*
Age (years)	40 ± 14	41.3 ± 16.1	0.902
Female, *n* (%)	98 (62%)	96 (62.7%)	0.355

IMID, immune-mediated inflammatory disease

occurred (Table 3). There was no significant difference in adverse events between the IMID patients receiving the CoronaVac vaccine vs. the recombinant protein subunit vaccine ZF2001 (19.5% vs. 14.3%, $P>0.05$). No disease flares occurred in the IMID group after vaccination (Table 4). Of note, there was one SLE patient with new-onset proteinuria according to the routine urine examination on the day after vaccination. However, because her other tests were normal (with a SLEDAI score of only 4) and the fact that she had recurrent proteinuria for 2 years before vaccination (urine protein never more than 1 g/24 h), we thought that her kidney disease was not in complete remission and we did not think that it was a flare of new-onset proteinuria after vaccination. In addition, the time interval between proteinuria and vaccination was too short to support the emergence of

Table 2 Treatments used for patients with IMIDs

IMID diagnosis, *n*	Immunosuppressive treatments, *n* (%)								
	GC	MTX	TNFi	CsA	Lef	HCQ	JAKi	MMF	SSZ
All IMIDs, *n* = 158	80 (50.6)	39 (24.7)	38 (24. 1)	7 (4.4)	24 (15.2)	69 (43.7)	5 (3.2)	16 (16.5)	16 (10. 1)
RA, *n* = 38	4 (10.5)	30 (78.9)	15 (39.5)	0	24 (63.2)	2 (5.3)	5(13.2)	0	2 (5.3)
AS, *n* = 33	0	5 (15.2)	23(69.7)	0	0	0	0	0	14 (42.4)
SLE, *n* = 77	70(90.9)	3 (3.9)	0	5 (6.5)	0	60 (77.9)	0	14 (18.2)	0
pSS, *n* = 9	5 (55.6)	0	0	2 (22.2)	0	7 (77.8)	0	2 (22.2)	0
Others, *n* = 1	1 (100)	1(100)	0	0	0	0	0	0	0

IMID Immune-mediated inflammatory disease, *GC* Glucocorticoid, *MTX* Methotrexate, *TNFi* Tumor necrosis factor alpha inhibitor, *CsA* Cyclosporine A, *Lef* Leflunomide, *HCQ* Hydroxychloroquine, *JAKi* Janus kinase inhibitor, *MMF* Mycophenolate mofetil, *SSZ* Sulfasalazine, *RA* Rheumatoid arthritis, *AS* Ankylosing spondylitis, *SLE* Systemic lupus erythematosus, *pSS* Primary Sjögren's syndrome

Table 3 Adverse events following vaccination in patients with IMIDs and healthy controls

	CoronaVac vaccine		*P*	ZF2001 vaccine		*P*
	IMID group (*n* = 123)	Control group (*n* = 122)		IMID group (*n* = 35)	Control group (*n* = 31)	
Adverse events, *n* (%)	24 (19.5)	62 (50.8)	0.000	5 (14.3)	6 (19.4)	0.581
Local reactions, *n* (%)	22 (17.9)	53 (43.4)	0.000	4 (11.4)	5 (16.1)	0.579
Pain	18 (14.6)	45 (36.9)	0.000	4 (11.4)	9 (29)	0.073
Swelling	5 (4. 1)	7 (5.7)	0.544	2 (5.7)	3 (9.7)	0.544
Erythema	5 (4.1)	6 (4.9)	0.747	0	1 (3.2)	0.284
Induration	3 (2.4)	4 (3.3)	0.693	1 (2.9)	0	0.343
Systemic reactions, *n* (%)	2 (1.6)	9 (7.4)	0.030	1 (2.9)	1 (3.2)	0.931
Myalgia	1 (0.8)	2 (1.6)	0.557	0	1 (3.2)	0.284
Fatigue	2 (1.6)	5 (4.1)	0.245	1 (3.2)	1 (3.2)	0.931
Fever	0	1 (0.8)	0.314	0	0	
Headache	1 (0.8)	4 (3.3)	0.172	0	0	
Shivering	0	0		0	0	

IMID Immune-mediated inflammatory disease

Table 4 Disease activity score before and after vaccination

IMID diagnosis		Before vaccination	30 days after vaccination	*P* value	Before vaccination	90 days after vaccination	*P* value
RA	DAS28	1.915	1.905	0.895	1.915	1.885	0.696
AS	ASDAS	1.03	1.09	0.352	1.03	1.05	0.776
SLE	SLEDAI	0.33	0.53	0.533	0.33	0.13	0.287

IMID Immune-mediated inflammatory disease

vaccine-induced proteinuria. Importantly, no participants had had COVID-19 during the study, so the incidence rate was 0% in both groups.

Discussion

Patients with IMIDs take long-term immunosuppressive drugs, such as glucocorticoids, biological agents, and immunosuppressants, which makes them predisposed to COVID-19. The American College of Rheumatology [3] recommends priority vaccination for Rheumatic and Musculoskeletal Diseases patients because they have a higher risk of COVID-19 and a worse outcome after infection than healthy controls. Studies also have shown that patients with rheumatic disease possess higher rates of hospitalization and severe illness after contracting COVID-19 [4, 5]. After the systemic rheumatic disease patients were vaccinated, their prognosis was better than that of unvaccinated patients, and the hospitalization rate and mortality were significantly reduced [6]. In some studies, it has been shown that SLE, pSS, and vasculitis patients may have more severe courses of COVID-19, and the use of prednisone at doses of ≥ 10 mg/day, mycophenolate mofetil, and rituximab has been associated with poorer outcomes [5, 7–11]. Therefore, vaccination may be more necessary for such patients to reduce the risk of contracting COVID-19 and to avoid serious adverse outcomes.

Vaccine efficacy, safety, immunogenicity must be carefully studied. Safety, which is mainly represented by vaccine-related side effects and the risk of IMID disease activity, is a possible factor for the hesitancy of patients with systemic autoimmune rheumatic disease to receive vaccination [12]. There are some reports of adverse events from COVID-19 vaccines. On March 18, 2021, the European Medicines Agency announced the discovery of thrombosis with thrombocytopenia syndrome following the administration of the ChAdOx1 nCoV-19 vaccine (Vaxzevria, Oxford/AstraZeneca), which uses a recombinant replication-defective chimpanzee adenovirus vector [13]. After six cases of cerebral venous sinus thrombosis with thrombocytopenia were reported among Janssen vaccine recipients between April 13 and 23, 2021, the US Centers for Disease Control and Federal Drug Administration recommended suspending the use of the Janssen vaccine [14], but there were no IMID patients in those case reports. According to previous experiences of vaccination in IMID patients, including vaccines against influenza, hepatitis B and hepatitis A, no serious adverse events like herpes rash, pneumonia, human papillomavirus, and tickborne encephalitis have been observed [15]. Similarly, COVID-19 vaccines, whether in inactivated or mRNA forms, have been shown to be safe for IMID patients in studies with a relatively large sample size [16, 17]. Although two patients died several weeks after vaccination in a multicenter study of mRNA vaccination of patients with autoimmune rheumatic diseases, the deaths were both irrelevant to the vaccines themselves [16].

However, mRNA vaccination seems to result in an increased incidence of herpes zoster virus among patients with IMIDs. For example, Furer et al. [18] have reported that the incidence of herpes zoster after BNT162b2 mRNA COVID-19 vaccination among IMID patients ($n=491$) was 1.2%, while that in the control group ($n=99$) was 0%. No herpes zoster virus infection was observed in our study, whether the participants were inoculated with inactivated vaccine or the recombinant subunit vaccine. In addition, Machado et al. have reported that adverse events were observed in 37% of cases, with serious events in 0.5%, and SARS-CoV-2 vaccines were safe for rheumatic and musculoskeletal disease (RMD) patients [19]. Likewise, in our study, the prevalence of adverse events in the IMID group was 18.4%, and no serious adverse events occurred. Interestingly, the incidence of adverse events in the IMID group was less than that in the control group, which may be due to the use of nonsteroidal anti-inflammatory drugs and glucocorticoids. Overall, IMID patients who received COVID-19 vaccines rarely experience vaccine-related side effects.

Do COVID-19 vaccines induce autoimmune diseases? Do they cause stable autoimmune diseases to flare? Theoretically, vaccination may induce an autoimmune disease flare, which is probably caused by molecular mimicry of the vaccine components, overstimulation of the immune system, and pathogenic effects of adjuvants. According to previous studies, there have been sporadic cases showing SLE disease flares after vaccination. For instance, Li et al. [20] have reported two cases of women presenting with SLE after measles vaccination. Moreover, Soybilgic et al. [21] have demonstrated that the disease recurrence rate among SLE patients after human papillomavirus (HPV) vaccination reached 30%, while no increase in the risk of disease activity in RMD patients was detected. Furthermore, Milanovic et al. [22] observed that no significant worsening of underlying disease occurred after influenza vaccination in 47 patients with SLE, RA, or pSS compared with 52 controls. Additionally, a large cohort study by Miranda et al. [23] showed that there was no difference in the probability of SLE between individuals who received the HPV vaccine and those who were not vaccinated. In a study with a large sample size, there were also no cases of disease activity in IMID patients who received mRNA COVID-19 vaccines [16]; however, no data on the disease activity related to CoronaVac have been reported [17]. In another study [19], there were

rare reports of an inflammatory/autoimmune rheumatic and musculoskeletal disease (I-RMD) flare after vaccination (Pfizer/BioNTech vaccine, AstraZeneca/Oxford, and Moderna vaccine). A flare following vaccination was reported in 4.4% of I-RMD cases, with 29 cases (0.6%) of severe flares, implying that a higher disease activity may be associated with a higher flare rate.

In our study, none of the patients showed significant IMID activity. Noticeably, there was one SLE patient who developed new-onset proteinuria after vaccination. This patient had a SLEDAI score of 4 and had repeated proteinuria before vaccination, which means that her kidney disease was not in complete remission, and there were no other changes in her disease at the end of the follow-up. Therefore, this case was considered as no disease activity. All patients in our study ensured disease stability for at least three months before vaccination, and our results suggest that the likelihood of disease activity occurrence after vaccination is extremely low. In sum, although there is a theoretical risk of disease activity after receiving a COVID-19 vaccine, the benefits of vaccination overweigh the risks of disease activity and side effects.

Due to the long-term use of glucocorticoids and immunosuppressive drugs, IMID patients are immunosuppressed, which may lead to a decreased vaccine efficacy. Our data showed that there were no cases of COVID-19 in the two groups, which supports the protective effects of vaccination against COVID-19, no matter which vaccine is utilized. In a phase IV trial of CoronaVac [17], the seroconversion(SC) and the positive rate of neutralizing antibody in the autoimmune rheumatic diseases group were less than those in the control group (70.4% vs. 95.5% and 56.3% vs. 79.3%, respectively), and the rate of seropositivity of the mRNA vaccine among autoimmune rheumatic disease patients also was less than that of the healthy controls (86% vs. 100%) [16], which suggests the low immunogenicity of the COVID-19 vaccine in autoimmune rheumatic disease patients. Additionally, a phase IV clinical study of CoronaVac revealed that patients with autoimmune rheumatic diseases receiving biologics, rituximab, or abatacept had the greatest negative impact on immunogenicity [17], which was attributed to drug-induced immunogenicity. Among the immunosuppressive drugs, methotrexate and mycophenolate mofetil had the greatest negative impact on immunogenicity.

Our study had some limitations that must be addressed. On the one hand, only the COVID-19 rate after vaccination was utilized to evaluate the efficacy of the vaccine, while the levels of neutralizing antibodies and anti-SARS-CoV-2 IgG were not tested due to the restricted conditions in our center. In addition, the sample size of this study was insufficient, and a study with a much larger sample size will be conducted in the future.

Conclusion

COVID-19 vaccination is safe for subjects with IMIDs, the adverse events are mild, and the vaccine does not increase the risk of disease activity. Meanwhile, COVID-19 vaccines can effectively reduce the incidence of this disease in IMID patients. In the future, studies with a larger sample size and a longer duration are needed.

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Author contributions
WY analyzed and interpreted the patient data regarding the IMIDs and the SARS-CoV-2 vaccines. LC and WY were responsible for follow-up and data collection, and WY and CJ were major contributors to writing the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials
All data generated or analyzed during this study are included in this published article.

Declarations

Ethics approval and consent to participate
The experimental protocol was established according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of Changsha Hospital of Traditional Chinese Medicine. Written informed consent was obtained from each participant or their guardian.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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