

Research article

COVID-19 vaccinations for patients with epilepsy in Guizhou Province, China: A cross-sectional study

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ARTICLE INFO

Keywords:
 COVID-19
 Vaccination
 epilepsy
 Adverse events
 Vaccine

ABSTRACT

Several COVID-19 vaccines have been approved for emergency use according to China's immunization programs. These vaccines has created hope for patients with epilepsy, because the vaccines can help to reduce their risk of becoming infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The aim of this study was to investigate the COVID-19 vaccine safety in patients with epilepsy. Here, we assessed the time of symptom control and the features of adverse events of seizure patients following their COVID-19 vaccinations. The results showed that adverse events of COVID-19 vaccinations for epilepsy patients included local pain at the injection site, dizziness and headache, epileptic attack, somnolence, limb weakness, limb pain, allergy, and fever. In addition, the average recovery time of the adverse events was approximately 42 h. More importantly, our study showed that it was relatively safe to vaccinate epilepsy patients who did not experience seizures for approximately 12 months prior to the immunization date.

1. Introduction

The risk of becoming infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a serious concern for persons with epilepsy worldwide [1]. The global threat of COVID-19 has greatly influenced the health conditions and daily lives of patients with epilepsy, such as a lack of timely medical services and disrupted use or supply of anti-seizure medications [2,3].

COVID-19 was first reported in December 2019 in Wuhan, Hubei Province, China [4]. Most infected patients have symptoms such as fever, dyspnea, dry cough, and tiredness. Patients infected with COVID-19 also may experience neurological symptoms, including seizures [5]. SARS-CoV-2 vaccines are now being developed using several different methods. A number of vaccines have received

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emergency use authorization from regulatory bodies in China.

Epilepsy is one of the sudden, most common, and recurring neurological disorders, affecting approximately 50 million people worldwide. Some studies have shown that SARS-CoV-2 infection may cause seizures [6]. COVID-19 worsens seizure control in patients with previously well-controlled seizures, and it also can trigger newly-onset seizures in patients with no known histories of seizures [7]. Twenty-seven out of 47 (57.4 %) patients developed status epilepticus after COVID-19 [8]. In addition, a higher percentage of death has been described in patients with active epilepsy affected by SARS-CoV-2 [9]. The mechanisms included a severe increase in neuronal excitability following an imbalance in ion channel functions. A severe disease course of COVID-19 can result in cerebrovascular events, cytokine storm, and hypoxic encephalopathy, which may trigger the development of acute seizures [10]. In addition, secondary seizures may be initiated after mitochondrial dysfunction, electrolyte imbalance, increased oxidative stress, and stroke in COVID-19 patients [11].

Because mass immunization has rapidly expanded, neurologists in the world now face the challenge of advising epilepsy patients on whether they should receive the vaccine. Some studies reported higher vaccine hesitancy in epilepsy patients than in healthy populations [2]. However, there have been only a few studies describing the adverse events of COVID-19 vaccination in epilepsy patients [12–14]. One study in a German tertiary epilepsy center reported that vaccinating against COVID-19 in epilepsy patients was safe and well-tolerated [12]. The second study from China showed that the post-vaccination effects in epilepsy patients was no higher than in controls. In addition, this study found no evidence suggesting worsening seizures after vaccination [13]. The third study showed that the two vaccines under consideration (ChAdOx1nCoV-19 and BNT162b2) had a low risk of worse epilepsy and a good safety profile among a cohort of epilepsy patients in Kuwait [14]. However, these studies did not report the average recovery times of adverse events. In addition, there has been no study describing the length of time necessary before seizure-free COVID-19 vaccinations among epilepsy patients. Hence, we assessed the time of symptom control and the features of adverse events of 194 epilepsy patients who were vaccinated against COVID-19, which provided an important reference for vaccine injection of these patients. The aim of this study was to investigate the COVID-19 vaccine safety in patients with epilepsy.

2. Methods

2.1. Patients and data acquisition

A cross-sectional study was conducted in this study. First, clinical data on COVID-19 vaccinations and epilepsy were obtained via an interview and structured questionnaire. The questionnaire included two general questions (sex, age), four epilepsy specific questions (age of disease onset, course of disease, use of anti-seizure medications), and five COVID-19 vaccination specific questions (type of vaccine, date of vaccination, duration of the seizure-free period before vaccination, seizure-related changes and the adverse events in the 1- month after the first dose of vaccine, and recovery times of adverse events) (Table 1). Second, the questionnaire was completed by patients, or with the help of their family if they had difficulty reading or writing. The patients were encouraged to complete the questionnaires in clinics. Then the questionnaire was administered by trained neurologists, specialized in epilepsy.

Patients previously diagnosed with epilepsy who visited our outpatient clinic at the Affiliated Hospital of Guizhou Medical University and Affiliated Hospital of Zunyi Medical University were recruited between March 1 and August 14, 2021. The inclusion criteria were as follows: (1) patients diagnosed with epilepsy according to the criteria proposed by the International League Against Epilepsy in 2017, (2) adult people (18 years or older) who were vaccinated with COVID-19 at the time of the visit, and (3) patients who did not change their medication for epilepsy 1 week before COVID-19 vaccination. The exclusion criteria included patients of epilepsy who unable to answer the questionnaire, unwillingness to participate in the study, and without detailed information. The ethics committees of the Affiliated Hospital of Guizhou Medical University approved all procedures (No.2021 [406]). The primary outcome was the safe time for epilepsy patients to get vaccinated with COVID-19. The secondary outcomes were the time of symptom control and the features of adverse events of seizure patients following their COVID-19 vaccinations.

In the period of study, a total of 1145 patients were admitted to our clinic and screened for participation to the study, including 432 patients managed by the Affiliated Hospital of Guizhou Medical University and 713 patients managed by the Affiliated Hospital of Zunyi Medical University. However, five samples were excluded because three patients did not provide durations of the seizure-free periods before vaccinations, and two patients did not provide the recovery times of adverse events after COVID-19 vaccinations (Fig. 1).

Table 1
The survey.

Age
Gender
Date of epilepsy diagnosis
Anti-seizure medications the patients are taking
Duration of the seizure-free period before vaccination
Epilepsy course
Date to get vaccination
Type of COVID-19 vaccine
Adverse effects after COVID-19 vaccination
Recovery time of your adverse effects after COVID-19 vaccination
Is there any seizure-related changes after COVID-19 vaccination

Three types of COVID-19 vaccines were approved in China at the time of the study: adenovirus vector vaccine, inactivated vaccine, and recombinant subunit vaccine. The adenovirus vector vaccine, also called convidecia vaccine, was from CanSino Biologics (Tianjin, China). The inactivated vaccine included Sinopharm (Vero Cell)-inactivated, COVID vaccine (Beijing Institute of Biological Products, Beijing, China), and the Sinovac inactivated COVID-19 vaccine (Vero cells) (Sinovac Life Sciences, Beijing, China). The recombinant subunit vaccine (CHO cells), also called ZF2001, was from Anhui ZhifeiLongcom Biopharmaceutical (Hefei, China). Adenovirus vector vaccine required only one injection. Inactivated vaccine required two injections, with an interval of more than 3 weeks, and the second dose was completed within 8 weeks. The recombinant subunit vaccine required three doses, with an interval of more than 4 weeks. The second and third dose should be completed within 8 weeks and 6 months after the first dose, respectively.

2.2. Statistical analysis

Statistical analyses were performed using SPSS statistical software for Windows, version 24.0 (SPSS, Chicago, IL, USA). For continuous variables, the mean (standard deviation) and median (minimum and maximum) are stated, whereas categorical variables are expressed as frequencies and percentages. The independent sample *t*-test was used for analyses of general data which were continuous variables and consistent with normal distributions. If continuous variables were not normally distributed, so the Mann-Whitney *U* test was used to analyze nonparametric distributions. The χ^2 test was used for binary variables. A probability value of $P < 0.05$ was considered to be statistically significant.

3. Results

3.1. Characteristics of patients

For the above mentioned patients, a total of 199 patients were vaccinated with COVID-19 vaccine, with a vaccination percentage of 17.37 %. However, five samples were excluded because no detail information. Hence, a total of 194 patients met the inclusion criteria and were participated to the study. Baseline patients and features of adverse events after COVID-19 vaccinations are shown in Table 2.

There were 88 males and 106 females treated with COVID-19 vaccine in our study. The mean ages of these patients with or without adverse events after COVID-19 vaccination were 30.02 ± 11.00 years and 30.00 ± 11.34 years, respectively ($P = 0.993$), indicating no significant difference in sex and age. The mean course of epilepsy of these patients with or without adverse events after COVID-19 vaccination were 6.74 ± 9.65 and 6.97 ± 7.26 years, respectively ($P = 0.282$). In addition, the anti-seizure medications used in these patients included sodium valproic acid, magnesium valproic acid, oxcarbazepine, levetiracetam, lamotrigine, topiramate, carbamazepine, and lacosamide. There was no significant difference in the numbers of anti-seizure medications ($P = 0.237$) and the types of vaccines ($P = 0.866$).

There were 27, 146, and 21 patients treated with recombinant vaccine (CHO cells), inactivated vaccine, and adenovirus vector vaccine, respectively. The type of vaccine used to treat these patients showed no significant difference in groups or in adverse events ($P = 0.866$).

3.2. Features of adverse events after COVID-19 vaccinations

Among these 194 patients, 67 patients (34.54 %) suffered from adverse events in the 1-month after the first dose of vaccines such as local pain at the injection site (65.67 %), dizziness and headache (13.43 %), epileptic attack (4.48 %), somnolence (7.46 %), limb weakness (2.99 %), limb pain (1.49 %), allergy (2.99 %), and fever (1.49 %) (Fig. 2). These results indicated that local pain at the injection site was the most common adverse event after COVID-19 vaccinations in patients with epilepsy, although most of the patients had no adverse events. Among these participants, three patients suffered from post-vaccine seizure-like symptoms. The first was a 22-year-old male with a 13-year history of epilepsy, who was treated with carbamazepine. This patient had an increased frequency of seizures in the 1-week after his first inactivated vaccine injection. The second was a 26-year-old female with a 9-year history of

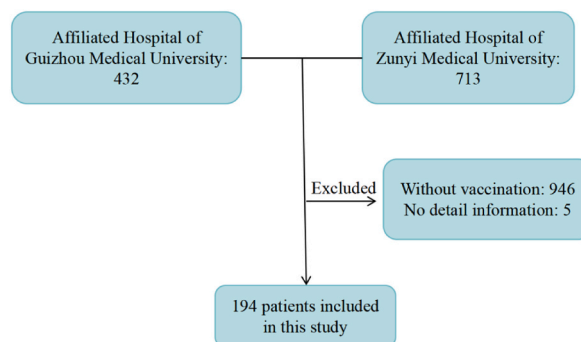
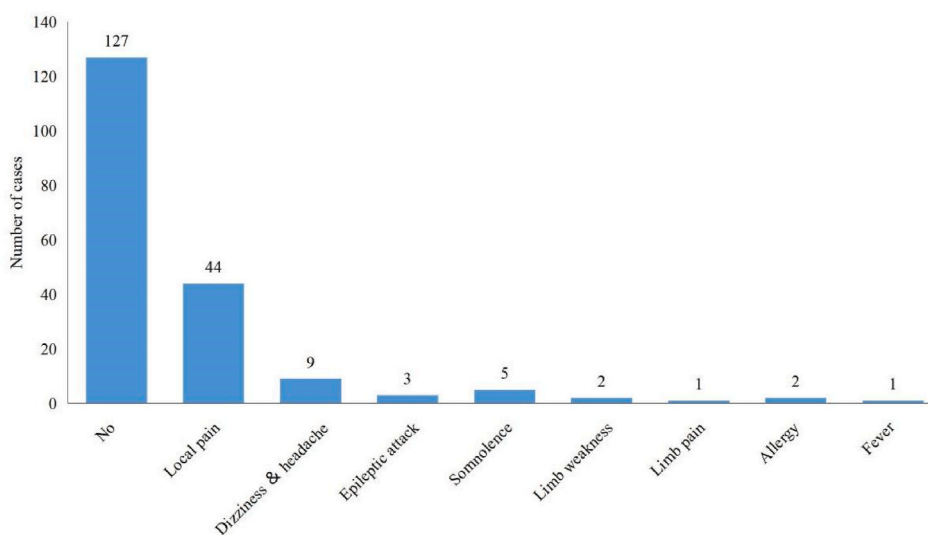


Fig. 1. The flowchart of recruiting patients.

Table 2

The basic characteristics of patients with epilepsy after COVID-19 vaccination in the survey.

	Without adverse effects (N = 127)	With adverse effects (N = 67)	P values
Age (mean \pm sd)	30.02 \pm 11.00	30.00 \pm 11.34	0.993
Gender			0.017
Male	66 (52.0)	22 (32.8)	
Female	61 (48.0)	45 (67.2)	
Numbers of Medicines			0.237
1	93 (73.2)	47 (70.1)	
2	28 (22.0)	16 (23.9)	
≥ 3	6 (4.7)	4 (4.0)	
Course of epilepsy M (P25, P75) (years)	3.98 (1.53, 8.76)	4.08 (2.34, 9.24)	0.27
Type of vaccine			0.866
Adenovirus vector vaccine	12 (9.5)	9 (13.4)	
Inactivated vaccine	94 (74.0)	52 (77.6)	
Recombinant subunit vaccine (CHO cells)	21 (16.5)	6 (9.0)	

**Fig. 2.** Adverse events of patients with epilepsy following their COVID-19 vaccination.

epilepsy, who was treated with carbamazepine, and who reported one seizure 3 days after her first inactivated vaccine injection. Another patient was a 40-year-old male with a 1-year history of epilepsy, who was treated with oxcarbazepine. This patient also reported one seizure after his first inactivated vaccine injection. All patients suffered from previous seizure patterns. They did not report any changes of duration in the ictal or post-ictal phase, and no status epilepticus was reported in this study.

The different numbers of anti-seizure medications in patients with epilepsy resulted in different adverse events after COVID-19 vaccinations. Fig. 3 shows the adverse events after COVID-19 vaccinations in patients with epilepsy, who were treated with different numbers of anti-seizure medications. A total of 33.57 %, 36.36 %, and 25 % patients suffered from adverse events in patients treated with one, two, and three anti-seizure medications, respectively. Furthermore, two patients treated with four anti-seizure medications both suffered from adverse events.

The median of seizure-free durations before vaccinations in the group with adverse events and the group without adverse events were 11 months and 12 months, respectively ($P = 0.89$) (Fig. 4), which showed no statistically significant difference. The range of seizure-free durations in the group without adverse events was 1–70 months. The mean seizure-free durations before vaccinations in groups with local pain at the injection site, dizziness and headache, epileptic attack, somnolence, limb weakness, limb pain, allergy, and fever were 16.46, 17.30, 12.11, 15.67, 16.20, 36.00, 1.00, 13.00, 15.00 months, respectively.

The median epilepsy courses with or without adverse events after COVID-19 vaccinations were 4.08 years and 3.98 years, respectively ($P = 0.27$) (Fig. 5), with no statistical difference in the two groups.

The mean recovery time of adverse events was 42.27 ± 94.74 h. The different recovery times of different adverse events after COVID-19 vaccinations are shown in Fig. 6. The average recovery times of different adverse events such as local pain at the injection site, dizziness and headache, epileptic attack, somnolence, limb weakness, limb pain, allergy, and fever were 25.23, 20.67, 24.00, 163.20, 24.00, 252.00, and 48 h, respectively.

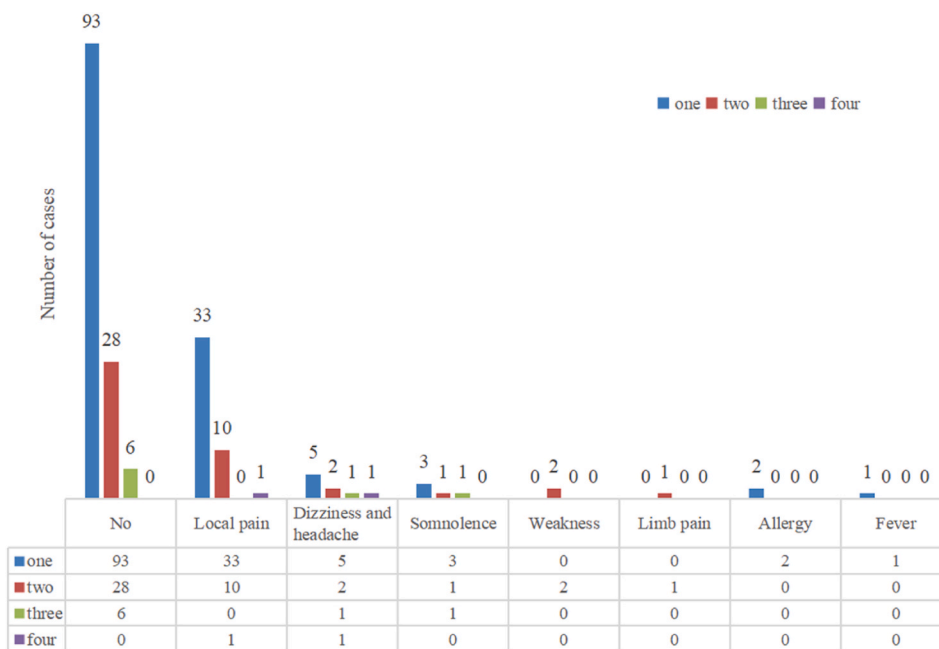


Fig. 3. Adverse events characteristics after COVID-19 vaccination in patients with epilepsy according to the numbers of drugs. One, two, three, four represent number of anti-seizure medications.

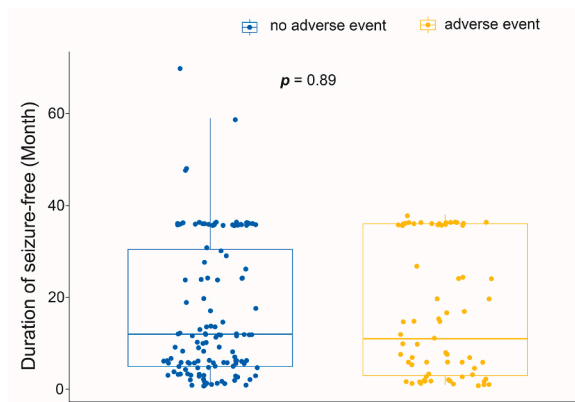


Fig. 4. Duration of seizure-free duration before vaccination in the group with adverse events and group without adverse events.

4. Discussion

The rapid spread of the SARS-CoV-2 pandemic poses particular challenges to the management of patients with epilepsy. A high acceptance of COVID-19 vaccination was present in the Chinese population during the pandemic, although safety concerns may have at least partially hindered the promotion of vaccine injections [15]. Hence, it is important to investigate the safety of COVID-19 vaccines for patients with epilepsy. In our study, we estimated the clinical features and safety for COVID-19 vaccines in epilepsy patients in Guizhou Province of China.

We found that the vaccination percentage of epilepsy patients was approximately 16.94 %. The low vaccination percentage in patients with epilepsy may have been due to concerns about vaccine safety. One study showed that most patients with epilepsy was unwilling to receive the COVID-19 vaccination, especially because of doubts about its safety and efficacy [2]. Approximately a third of patients unwilling to be vaccinated thought they could not receive the vaccine because of epilepsy. Another study showed that 27 % of the physicians believed that patients with epilepsy were at increased risk of contracting COVID-19 [16]. However, epilepsy is not listed as a contraindication for COVID-19 vaccination in China. In addition, there have been only a few studies describing the adverse events of COVID-19 vaccination in epilepsy patients. This uncertainty and ambiguity might have led to the low vaccination rate in patients with epilepsy.

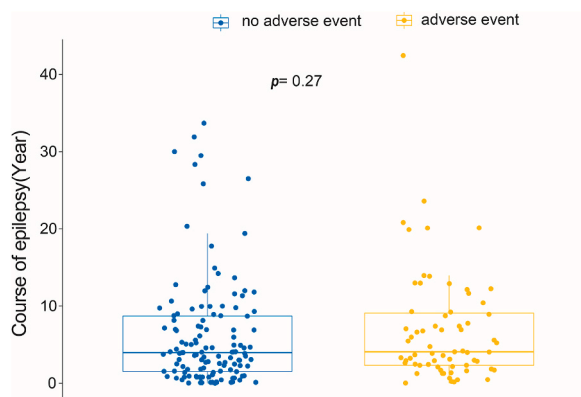


Fig. 5. Average course of epilepsy in different adverse events after COVID-19 vaccination.

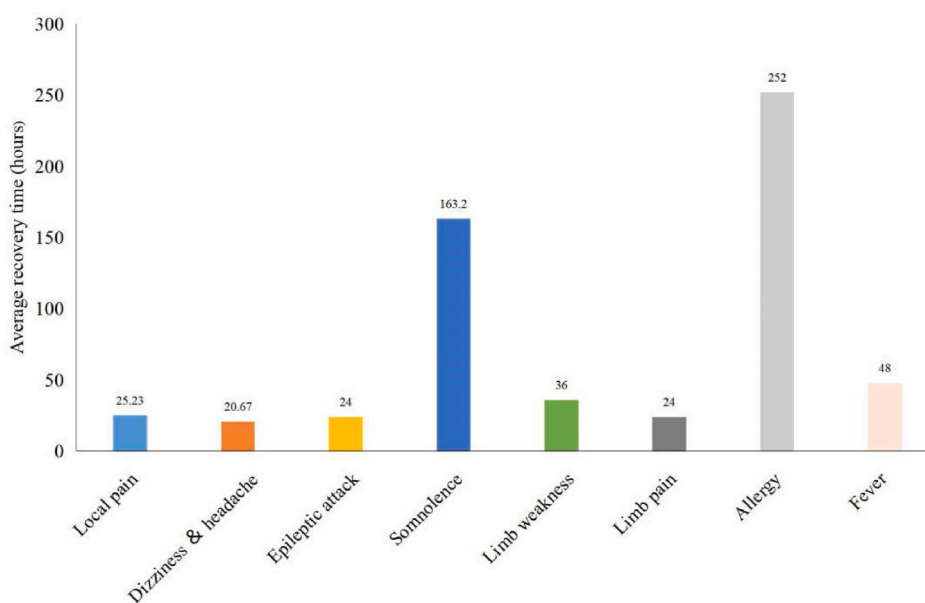


Fig. 6. Average recovery time of different adverse events after COVID-19 vaccination.

Consistent with previous studies, our study showed that the most common adverse event was pain at the injection site [12–14]. Dizziness and headache, and somnolence were the second most common adverse events. Epileptic attack, limb weakness, limb pain, allergy, and fever were relatively rare adverse events. Adverse events of COVID-19 vaccination in the general population also included status migrainosus and cerebral vein thrombosis [17,18]. These are rare adverse events of COVID-19 vaccine. It is possible that the sample size in our study was small, so these rare adverse event was not observed in our patients.

Among these patients, three patients suffered from seizure-like attacks after vaccination. The first patient was a 22-year-old male with a 13-year history of epilepsy, who was treated with carbamazepine. We reviewed his medical history and found that the patient had two seizures within 1 month of vaccination, occurring on the 10th and 18th day after vaccination. We speculated that the patient had poor control of his epilepsy, so the seizures may not have been related to vaccine injections, although definitive evidence in support of this hypothesis is lacking. The second case was a 26-year-old female with a 9-year history of epilepsy, who was treated with carbamazepine, and who reported one seizure 3 days after her first inactivated vaccine injection. The third patient was a 40-year-old male with a 1-year history of epilepsy, who was treated with oxcarbazepine. This patient also reported one seizure after his first inactivated vaccine injection. It is unknown whether seizures in these patients were related to COVID-19 vaccinations. Rare cases of focal onset seizures with transient episodic behavioral abnormalities following the first injection of COVID-19 vaccine have been reported [19]. We therefore classified the seizures as side effects, although the exact mechanism for this phenomenon is unclear. Hence, further study on the relationship between COVID-19 vaccination and epilepsy needs to be conducted.

The course of epilepsy in the group with adverse events and without adverse events showed no statistically significant difference. In addition, the average recovery time of adverse events was approximately 42 h. A previous study reported that the majority of reported

adverse events following COVID-19 vaccinations were mild to moderate, and occurred within 24 h after vaccination. The most frequently reported adverse events included fatigue, fever, general body ache, shortness of breath, epigastric pain, and headache. However, there were five serious events, which included cardiac arrest, pulmonary embolism, and cerebral venous sinus thrombosis [20]. Our patients did not suffer from these serious events. In addition, there have been no studies reporting the recovery times of adverse events after vaccination.

There are many questions that concern epilepsy patients in the clinic. For example, if epilepsy patients can be vaccinated against COVID-19, when can epilepsy patients be vaccinated against COVID-19 for optimal immunization? Hence, it is very important to identify the safe seizure-free duration before vaccination. In this study, there was no significant difference of seizure-free durations before vaccination in the group with adverse events and the group without adverse events. In addition, the median of the seizure-free duration before vaccination in the group without adverse events was 12 months, suggesting it was relatively safe to vaccinate epilepsy patients who had not had seizures over 12 months. These results provided an important reference for the vaccination schedule of these patients.

One patient in our study suffered from fever (100.76 °F) after COVID-19 vaccination, but it did not lead to seizures, although fever can be a cause of seizure attacks. In her medical history, the period with no seizures was 2.5 years, during which time she was treated with sodium valproate. We speculated that good control of epilepsy may be an important reason for the lack of seizures following her fever after vaccination.

4.1. Limitations

There were some limitations to our study. First, this was a cross-sectional study, and although some patients were vaccinated, they were unwilling to answer the questionnaire, which may have led to a statistical bias, such as those with low vaccination rates and limited records of side effects. Second, due to the nature of the cross-sectional study, the vaccination time of each patient may have differed from their patient responses. Our data may therefore represent short-term adverse event, and not long-term adverse event, which is also a concern. Third, we did not analyze the type/severity of seizure of each patient in our study, which may cause us to ignore the differences between different type/severity of seizure.

5. Conclusions

Taken together, we encourage neurologists to recommend COVID-19 vaccination with approved vaccines to their epilepsy patients who had not had seizures over 12 months, unless there was a specific contraindication. We recommend that persons with epilepsy discuss the vaccine with their physicians before COVID-19 vaccination. In addition, it is important that epilepsy patients continue to follow public health guidelines to reduce exposure and spread of COVID-19, even after vaccination.

Ethic declaration

This study was approved by the ethics committees of the Affiliated Hospital of Guizhou Medical University (No.2021 [406]). The study was conducted according to established ethical guidelines and written informed consent obtained from all patients.

Funding

This work was supported by National Natural Science Foundation of China (No. 81860248; No. 81960224), the Basic Research Program of Guizhou Province (Qiankehe basic-ZK [2023]395 and 324), and the cultivate project 2021 for National Natural Science Foundation of China, Affiliated Hospital of Guizhou Medical University (No.gyfynsc-2021-14).

Data availability statement

All data can be obtained by contacting the corresponding authors.

CRedit authorship contribution statement

Qian Zheng: Writing – original draft, Funding acquisition, Data curation. **Yong-Ran Cheng:** Visualization, Methodology, Formal analysis. **Mingwei Wang:** Visualization, Software, Methodology, Formal analysis. **Xuntai Ma:** Validation, Supervision, Methodology. **Lan Ye:** Methodology, Investigation, Conceptualization. **Zucaï Xu:** Writing – review & editing, Investigation, Data curation. **Zhanhui Feng:** Writing – review & editing, Visualization, Validation, Project administration, Funding acquisition, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank all the participants of this study.

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