COVID-19 Vaccine Take-up Rate, Safety and Tolerability in Patients with Epilepsy

Firdevs Ezgi Uçan Tokuç[1], Fatma Genç[1], Yasemin Biçer Gömceli[2]

[1]University of Health Sciences Turkey, Antalya Training and Research Hospital, Clinic of Neurology, Antalya, Turkey
[2]Memorial Antalya Hospital, Clinic of Neurology, Antalya, Turkey

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Corresponding Author: Firdevs Ezgi Uçan Tokuç MD, E-mail: ezgiucan@gmail.com
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Abstract

Objective: Although vaccines are considered safe for most people, patients with some chronic diseases have been very hesitant to get vaccinated, especially at the initial stages of vaccination. We conducted a survey among patients with epilepsy (PWE) who are currently experiencing hesitations, aiming to investigate the vaccination rates against Coronavirus disease-2019 (COVID-19) and the side effects emerged in vaccinated patients.

Methods: Two hundred nineteen PWE were questioned during a routine outpatient follow-up through previously prepared questionnaires that contained questions about patients' demographic features, information about the vaccination status, and its adverse effects.

Results: We included 219 PWE in the study of which 112 (51.1%) were female and 107 (48.8%) were male. One hundred eighty patients (82.1%) had been vaccinated at least once, 75% of the patients preferred two doses of BNT162b2 mRNA COVID-19 vaccine, 9.4% of the patients preferred two doses of Sinovac's inactivated vaccine, 6.1% of the patients preferred three doses of Sinovac, and 9.4% of the patients preferred Sinovac and BNT162b2 vaccines. Seventy-seven (42.7%) patients reported that they experienced side effects after vaccination whereas ten patients (5.5%) reported worsening of their seizures after vaccination; one person stated that she/he was hospitalized in the intensive care unit due to status epilepticus.

Conclusion: Generally, the tolerance of COVID-19 vaccines has progressed with mild side effects in most cases, which is consistent with previous studies in the general population, similarly no serious and previously unreported side effects were found in our study. Our study showed that COVID-19 vaccines are well-tolerated and safe for seizures in PWE.

Keywords: Epilepsy, COVID-19 vaccination, Pfizer BioNTech, Sinovac-CoronaVac, side effect

INTRODUCTION

Due to the Coronavirus disease-2019 (COVID-19), which has more than 400 million cases to date, approximately 6 million deaths have occurred around the worldwide and approximately 100 thousand deaths in Turkey.[1] This disease, which causes a socioeconomic burden as well as serious health problems, has massively impacted global public health, and vaccination studies have started rapidly since the first day of the pandemic to prevent COVID-19, particularly severe disease. As of December 2022, 13 trillion vaccinations have achieved all over the worldwide and 139 million in Turkey, and vaccination started with Sinovac vaccine in Turkey, then continued with Pfizer BioNTech and finally Turkovac vaccine.[1] Owing to the vaccines developed at an extremely rapid pace, there was a reduction in the symptoms of COVID-19-related diseases and a decrease in hospitalizations and intensive care unit admissions.[2,3] Although the vaccine is considered safe for most people, patients with some chronic diseases have been very hesitant to get vaccinated, especially in the early stages of vaccination. Patients with epilepsy (PWE), one of the disease groups highly affected by the pandemic, were also the most hesitated group. The International League Against Epilepsy (ILAE) stated that there is no evidence associated with a high risk of side effects due to the COVID-19 vaccine in PWE, but in some countries having uncontrolled epilepsy is listed as a contraindication.[4] Especially at the beginning of vaccination in our country, in some centers, there were opinions that if patients had epilepsy, they should not be vaccinated. We conducted a survey among PWE who were currently experiencing hesitations, aiming to investigate the vaccination rates against COVID-19, the side effects emerged in vaccinated patients, the effect of the vaccine on epileptic attacks, and the reasons why unvaccinated PWE did not get vaccinated.

METHODS

This cross-sectional study was conducted in the Antalya Training and Research Hospital, which is a tertiary center in Turkey. Between November and December 2021, 219 PWE over the age of 18 who were diagnosed with epilepsy according to the ILAE guideline, and followed up in the epilepsy outpatient clinic of Antalya Training and Research Hospital were included in the study.

Patients with severe mental retardation who cannot express themselves, who do not have regular outpatient follow-up, and whose epilepsy diagnosis is unclear were excluded.

Patients were asked questions through previously prepared questionnaires during routine outpatient follow-up. The survey questions of 3 groups:

1. In addition to questions about demographic data such as age-gender-occupation of the patients, seizure types, seizure frequencies, and drugs they used were questioned. The seizure types of the patients were categorized according to the ILAE epilepsy classification 2017 guidelines.

2. The vaccination status of the patients was questioned and the reason for not being vaccinated and whether they were considering vaccination were also noted.

3. The status of vaccinated patients with COVID-19 infection before vaccination was recorded. Additionally, the frequency of vaccination, the type of vaccine, the local and systemic side effects experienced after each vaccine, as well as serious side effects that may cause hospitalization or disability were questioned. If there were any changes in the seizures of patients after vaccination were also questioned. Based on the seizure diaries kept by the patients, an increase of more than 50% in the frequency of seizures after vaccination compared to pre-vaccination, the emergence of new seizure types after vaccination, or the prolongation of seizure durations by more than 50% compared to the past or the presence of status epilepticus were recorded as an increase in the frequency of seizures.

The Ethics Committee of Antalya Training and Research Hospital (approval number: 16/13, date: 14/10/2021) approved this cross-sectional study, and written informed consent forms were obtained from all patients.

Statistical Analysis

All statistical analyses were performed using Statistical Package for the Social Sciences 22.0. Categorical variables were described as percentages, and continuous variables were described using mean±standard deviation. Means for continuous variables were compared using independent group t-tests when the data were normally distributed. Categorical variables analyzed by chi-square or Fisher's exact tests and p value of 0.05 or below were treated as significant.

RESULTS

The mean age of 219 PWE included in the study was 37.9±13.5 years, of which 112 (51.1%) were female and 107 (48.8%) were male. Eight (3.6%) patients were illiterate, 109 (49.9%) were primary school graduates, 59 (26.9%) were high school graduates, and 43 (19.6%) were university graduates. One hundred and five (47.9%) patients were employed, and 114 (52.1%) patients were unemployed at the time of the survey.

Of the patients, 157 (71.6%) were in focal epilepsy, 38 (17.3%) were in generalized epilepsy, 24 (10.9%) were in the unclassified group, and 116 of these patients were followed up without seizure. One hundred thirty (59.3%) patients have been receiving monotherapy, and 89 (40.6%) patients have been on polytherapy. Demographic data for all patients are presented in Table 1.

In total, 180 patients (82.1%) had been vaccinated at least once. At the time of our study, only Pfizer BioNTech (BNT162b2) and Sinovac-CoronaVac (Sinovac) vaccines were available in Turkey. In this context, when evaluated in terms of the vaccine types preferred by the patients, 75% of the patients preferred 2 doses of BNT162b2, 9.4% of the patients preferred 2 doses of Sinovac, 6.1% of the patients preferred 3 doses of Sinovac, and 9.4% of the patients preferred both Sinovac and BNT162b2 vaccines (Table 2).

The reasons for unvaccinated patients not being vaccinated at the time of the survey were questioned. 35.8% of the patients stated that they would never be vaccinated, 32% were undecided, and 32% stated that they had a vaccine appointment. When the reasons of the patients who decided not to get vaccinated were examined and 10.2% reported that they were scared of the interaction of the vaccine they used with anti-seizure medication (ASM), 12.8% were afraid of the side effects that the vaccine could cause, 12.8%

Table 1. Demographic characteristics of the study group

Features	n	Percent (%)
Gender		
Male	107	48.8
Female	112	51.2
Marital status		
Married	120	54.7
Single	99	45.3
Education		
Illiterate	8	3.6
Primary education	109	49.9
High school	59	26.9
University	43	19.6
Job		
Working	105	47.9
Not working	114	52.1
Epilepsy type		
Focal epilepsy	157	71.6
Generalized epilepsy	38	17.3
Unknown	24	10.9
Epilepsy surgery		
Yes	3	1.3
No	216	98.6
Comorbidity		
Yes	54	24.6
No	165	75.3

MAIN POINTS

- No previously undescribed side effects were observed in patients with epilepsy (PWE) vaccinated with Coronavirus disease-2019 (COVID-19) vaccines.
- Our study showed that COVID-19 vaccines are well-tolerated.
- Our study showed that COVID-19 vaccines are safe in terms of not increasing the frequency of seizures in PWE.

did not feel the need to be vaccinated because they experienced COVID-19, 30.7% were afraid of triggering seizures after vaccination, and 33.3% reported that they would not be vaccinated for other reasons (Table 2).

When we analyzed the demographic data of vaccinated and unvaccinated PWE, the average age of unvaccinated patients was 32.1±11.3 years, and 22.3% of female patients and 13% of male patients were not vaccinated. According to the analysis, a statistically significant relationship was found between age and those who were vaccinated, and the vaccination rate increased as the age increased (p=0.003). Additionally, the relationship between vaccination and comorbidity was examined, and no statistically significant difference was observed (p=0.50). Demographic data of vaccinated and unvaccinated patients are given in Table 3.

Considering the side-effect rates of the vaccinated patients, 77 (42.7%) patients reported that they experienced side effects after vaccination. The most common side effects were pain and tenderness at the vaccination site (39.4%); others were; swelling at the injection site (1.6%), redness at the vaccination site (0.5%), post-vaccine fatigue (12.7%), myalgia (6.1%), fever (6.6%), arthralgia (1.6%), runny nose (0.5%), diarrhea (0.5%), and sore throat (1.1%). Side effects were most frequently observed in patients who received 2 doses of BNT162b2. The mean duration of the observed side effects was 1.8±2.72 days. While 10 patients (5.5%) reported worsening of their seizures after vaccination, 1 person stated that she/he was hospitalized in the intensive care unit due to status epilepticus Although the patient describing status epilepticus was approximately twelve h after vaccination, the exact time interval for patients reporting worsening seizures is unknown.

Of the 10 patients describing worsening of seizures, 7 received 2 doses of BNT162b2, 1 received Sinovac + BNT162b2, 1 received 2 doses of Sinovac, and 1 received 3 doses of Sinovac vaccine (Table 4).

Table 2. Vaccination characteristics of the patients included in the study

Features	n	Percent (%)
COVID-19 history		
Yes	192	87.6
No	27	12.3
Vaccination		
Yes	180	82.1
No	39	17.8
Vaccine type		
BNT162b2 2 doses	135	75
Sinovac 2 doses	17	9.4
Sinovac 3 doses	17	9.4
Sinovac + BNT162b2	11	6.1
Reason for not vaccinating		
Afraid of triggering seizures after vaccination	12	30.7
Had COVID-19 before	5	12.8
Afraid of the side effects	5	12.8
Afraid of the interaction with anti-seizure medication	4	10.2
Other	13	33.3

BNT162b2: BioNTech, COVID-19: Coronavirus disease-2019

No patients described serious side effects.

The clinical characteristics of the patients who experienced side effects were also examine; no statistically significant difference was observed between age, type of seizure, and number of anti-seizure drugs used due to comorbidity and having had COVID-19. In terms of gender, side effects were more common in females (p=0.0004). Demographic information of patients describing worsening of seizures is given in Table 4 and Table 5.

There was no statistical significance between age, vaccine type, seizure classification, and seizure frequency among patients who described and did not describe worsening in seizures, and again there was a statistically significant seizure frequency rate in female gender (p=0.02) (Table 5).

DISCUSSION

The COVID-19 vaccine started to be administered in our country on January 13, 2021, and serious indecisiveness was observed in society during the first days of vaccination. PWE also experienced hesitancy about getting vaccinated due to reasons such as; interaction with the ASM they use and fear of triggering seizures. Additionally, in some health centers where vaccination was administered at the beginning of the vaccination period, health workers had the same hesitations about PWE for an unknown reason and tended to refer patients to neurologists before vaccination. Due to these hesitations, the Turkish Epilepsy Society published a statement stating that there was no evidence of a high risk of side effects to the COVID-19 vaccines in individuals with epilepsy.[5] Additionally,

Table 3. Demographic comparison between vaccinated and unvaccinated group

Features	Vaccinated (n)	Unvaccinated (n)	p value
Age	39.1±13.6	32.1±11.3	0.003
Gender			0.07
Male	93 (86.9%)	14 (13.1%)	
Female	87 (77.6%)	25 (22.3%)	
Marital status			0.62
Single	100	20	
Married	80	19	
Education			0.18
Illiterate	7	1	
Primary education	93	26	
High school	43	16	
University	37	6	
Job			0.91
Working	86	19	
Not working	94	20	
Epilepsy type			0.08
Focal epilepsy	129	28	
Generalized epilepsy	28	10	
Unknown	23	1	
Comorbidity			0.50
Yes	46	8	
No	134	31	

Table 4. Features of ten patients who describe worsening of seizures

Patient	1	2	3	4	5	6	7	8	9	10
Age	39	43	57	39	38	43	23	36	24	55
Gender	M	F	F	F	F	F	F	M	F	F
Epilepsy duration	22	29	43	29	15	15	12	11	16	54
Number of anti-seizure medication	1	3	3	1	2	3	3	6	2	4
Seizure type	Focal	Focal	Focal	G	G	Focal	Focal	Focal	G	Focal
Seizure frequency	None	1/ 3 3 month	4-5/month	1/ 3 3 month	4-5/month	4-5/month	4-5/month	4-5/month	1/ 3 3 month	None
Comorbidity	No	No	No	No	No	DM	Mild MR	Intracranial mass	Mild MR	No
Had COVID-19 before	No	No	No	Yes	Yes	No	No	No	No	No
Vaccine type	2 dose B	2 dose S	2 dose B	S + B	2 dose B	2 dose B	2 dose B	3 dose S	2 dose B	2 dose B
Side effects	P, A	P, Fa, A	P, A	P, Fa, A	P, Fa, A, So	P, Fe, A, So	A	A	A	Fa, A, HA

M: Male, F: Female, Epilepsy duration: Year, FIAS: Focal impaired, Focal: Focal epilepsy, G: Generalized epilepsy, DM: Diabetes mellitus, MR: Mental retardation, B: BNT162b2, S: Sinovac, P: Pain, A: Arthralgia, Fa: Fatigue, So: Sore throat, Fe: Fever, HA: Headache, COVID-19: Coronavirus disease-2019

Table 5. Comparison of patients who described worsening/not worsening in their seizures

Features	Patients not describing worsening in seizures n=169	Patients describing worsening in seizures n=10	p value
Age	39.1±13.8	39.7±11.0	0.91
Gender			0.04
Male	90	2	
Female	79	8	
Marital status			0.35
Married	93	7	
Single	76	5	
Education			0.02
Illiterate	5	2	
Primary education	88	5	
High school	39	3	
University	37	0	
Job			0.62
Working	81	4	
Not working	88	6	
Epilepsy type			0.25
Focal epilepsy	121	7	
Generalized epilepsy	25	3	
Unknown	23	0	
Comorbidity			0.07
Yes	41	5	
No	128	5	
Vaccine type			0.96
BioNTech 2 doses	127	7	
Sinovac 2 doses	16	1	
Sinovac 3 doses	10	1	
Sinovac + BioNTech	16	1	

ILAE's view was that the risk of COVID-19 infection could be much more harmful than the risk of adverse effects from vaccines.[6]

In our hospital, which is a tertiary epilepsy center in Turkey, we presented real-life data including the reasons for vaccine hesitancy, side effects of vaccines, and the effects of vaccines on seizures of PWE.

At the time of our study, at least 2 dose vaccination rates in Turkey were around 83%, while this rate was around 79% in Antalya, and the vaccination rates of our patients were similar to the general population.[7] Generally, the tolerance of COVID-19 vaccines has progressed with mild side effects in most cases, which is consistent with the previous studies in the general population,[8,9] and no serious and previously unreported side effects were found in our study. When the mean duration of all vaccine-related systemic and local side effects was considered, it was observed as 1.8±2.7 days in our study, and similar durations were observed in the clinical trials of vaccines and in the literature.[9,10]

The most common side effect was pain/tenderness on the vaccinated arm (39.4%), which was observed more frequently after the BNT162b2 vaccine. Compared to the side effect rates observed in the clinical trials of both vaccine studies, it was found to be low.[8,10] Additionally, in a meta-analysis published by Lin et al.,[11] wide local side-effect rates were observed in vaccine studies conducted in PWE in various countries, and a similar rate of side effects was observed as in a study by Özdemir et al.[12] in Turkey (36%). This may be an ethnic difference, or, it may be because the patients cannot remember or can forget the side effects since our study was conducted retrospectively. This is a limitation of our study. Although the frequency of local side effects after BNT162b2 vaccine was higher in our study, in a study including 111 PWE vaccinated with Sinovac and BNT162b2 vaccines in Germany, side effect profiles and side effect frequencies of vaccines were compared and similar results were observed in both comparisons. Additionally, in that study, it was argued that the risk of worsening seizures after vaccination was minimal.[13] In our study, when the side effects and clinical features were compared, no correlation was observed with any factor other than female gender, including comorbidity. In a previous study conducted in a tertiary epilepsy

center in Germany, a significant difference between vaccine side effects and female gender, age, and early age of onset was observed. As in our study, no relationship could be found between the number of ASMs and vaccine side effects, and it has been argued that this might be because patients using a high number of ASMs attributed less value to side effects.[14]

There were 10 (5.5%) patients who described increased seizures after vaccination. One of these patients was a patient hospitalized in the intensive care unit due to status epilepticus. Since the same patient had non-epileptic seizures in addition to epileptic seizures, it was not possible to distinguish whether the seizures she/he described as an increase was non-epileptic or epileptic. Although it was previously reported that vaccines would not increase seizures, a slight increase in risk was reported only in childhood encephalopathies such as Dravet's syndrome.[15] However, although studies with new vaccines (mRNA) are limited, due to our experience, we think that the COVID-19 vaccine has no effect on seizures in PWE and there is no difference in the side-effect profile compared with the normal population, as stated in many studies. According to the literature, post-vaccine status epilepticus is not an expected side effect, but it is thought that the increase in seizures after vaccination is mostly coincidental or related to the natural course of the disease.[16] This rate was found to be slightly higher in female gender in patients with vaccine hesitancy, and when the relationship between the causes of hesitancy and comorbidities was examined, no statistically significant relationship was found. In a population-based study conducted in Brazil in 2022 to investigate COVID-19 vaccine hesitations and related factors by gender, vaccination rates were found to be slightly higher in males, in line with our study. Unlike our study, a correlation was observed between having comorbidity in the male gender group and having a high education level in the female gender, and hesitation about vaccination.[17] As one of the main findings of our study, it was determined that the indecision to get vaccinated decreased with age. We think that the possible reason for this may have been influenced by the fact that the COVID-19 epidemic has been more severe in the elderly and in the presence of comorbidities since the beginning of the epidemic. In a multicenter study conducted on patients who were not previously diagnosed with epilepsy, similar to our study, it was found that vaccine hesitancy decreased as age increased, and attention was drawn to the fact that elderly people were more likely to volunteer to be vaccinated due to fear of death.[18]

Study Limitations

Our study has some limitations. The number of PWEs included in the study was relatively small and no comparison could be made because there was no healthy control group. This leads to limitations in the comparison of side effects. Larger studies are needed to evaluate vaccine types, side effect profile, and tolerability in PWE.

CONCLUSION

In conclusion, our study showed that COVID-19 vaccines are well tolerated and safe for seizures in PWE.

Ethics

Ethics Committee Approval: The Ethics Committee of Antalya Training and Research Hospital, approval number: 16/13, the date: 14/10/2021.

Informed Consent: Consent form was filled out by all participants.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: F.E.U.T., F.G., Y.B.G., Concept: F.E.U.T., Design: F.E.U.T., Data Collection or Processing: F.G., Analysis or Interpretation: Y.B.G., Literature Search: F.E.U.T., Writing: F.E.U.T.

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