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ORIGINAL ARTICLE

A cross-sectional study of COVID-19 vaccination patterns among patients with epilepsy in Hong Kong

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Abstract

Objective: As Hong Kong faced the 5th wave of the COVID-19 pandemic, the facilitators and hurdles toward effective vaccination is important for healthcare professionals to understand the vaccination gap among patients with epilepsy.

Methods: A cross-sectional, pragmatic study of COVID-19 vaccination was performed at a tertiary epilepsy center with regards to patterns of vaccination and any unusually high rate of adverse events. Patients having recent visits at the epilepsy center (4 months) had their anonymized electronic linkage records examined 12 months after the inception of vaccination program for types of vaccines, seizure demographics, and adverse events following immunization (AEFI).

Results: A total of 200 patients with epilepsy and their anonymized data were analyzed. The vaccine uptake was approximately 60% of that of the general population. Twice as many patients with epilepsy chose to receive mRNA vaccine as compared with inactivated vaccine. The proportion of patients who kept up-to-date with all available dosing was 7%. Patients with epilepsy with genetic etiology were least likely to receive vaccination (13/38, 34%, $P = .02$). There was no unreasonably high rate of unacceptable side effects after vaccination among patients with epilepsy. Only 3 patients reported worsening of seizures without meeting the criteria for AEFI. Refractory epilepsy, allergy to antiseizure medications and elder age (≥65) did not confer any significant difference in vaccination patterns or adverse effects.

Significance: A vaccination gap exists among epilepsy patients which calls for actionable strategies for improving vaccine uptake, including education and outreach programs.

KEYWORDS
COVID-19, epilepsy, vaccines

1 | INTRODUCTION

In February 2022, Hong Kong entered the fifth wave of the COVID-19 pandemic. Patients with epilepsy, who are by the same token a category of patients with chronic diseases, are at risk of COVID-19 infection. Previous studies demonstrated that patients with epilepsy will likely suffer from an increase in the incidence of COVID-19 infection, with higher rates of mortality and morbidity.[1] Although a local study did not demonstrate the association of COVID-19 mortality with epilepsy (published in the early days of the COVID-19 pandemic), the underlying etiology of epilepsy is diverse, and those with, for instance, post-stroke epilepsy (under the precinct of a stroke etiology) will likely come under the heightened risk factor for COVID-19 mortality.[2] Indeed, the reverse (ie, SARS-CoV2 affecting epilepsy) is also true, whereby a Chinese study illustrated the effect of SARS-CoV2 exacerbating the existing seizure patterns of patients with chronic epilepsy.[3]

COVID-19 vaccination is a major step toward fighting the battle of COVID-19 pandemic. Local data already showed that vaccination significantly reduced mortality associated with the infection (ie, at least 5 times reduced fatality if an individual has received 2 doses).[4] A British epidemiological study also showed that, with vaccination, the mortality for neurological conditions including epilepsy would be in the region of 1.2–2.0-fold increases only.[5]

In Hong Kong, only two vaccines are available to the general public, namely Sinovac (CoronaVac®), which is an inactivated virus vaccine and BioNTech (BNT162b2), which is an mRNA vaccine. The rationale was based on availability (ie, sourcing issues) and the recommendation from the expert committee set up by the Government of Hong Kong Special Administrative Region (ie, based on scientific evidence). The choice covers the need for patients at large to choose between the two technologies. Moreover, if an individual cannot receive one vaccine for any reason (eg, allergy), then there is still a choice for another.

The uptake of vaccination among patients with epilepsy is variable across different populations with understandable differences due to cultural perceptions, the availability of vaccines and other logistic reasons. It may range from 10 to 70%.[6–8] Several factors of the conditions inherent among patients with epilepsy may be determinative of the vaccine hesitancy. This includes, but not limited to, the perceived likelihood of seizure clustering in the presence of post-vaccination fever, any potential trigger of status epilepticus, fear of worsening in some etiologies of epilepsy (eg, stroke, autoimmune diseases), and prior allergies to antiseizure medications. Other barriers may include more logistic issues such as the patients with epilepsy not having the resources and support to obtain vaccination, or lack of capacity in cases of intellectual disability. We would like to explore the vaccination patterns in a cross-sectional study with a view to exploring the facilitators and hurdles to COVID-19 vaccination.

Key points

- A vaccination gap exists in patients with epilepsy which calls for strategies to improve vaccine uptake, including education and outreach programs.
- Patients with epilepsy of genetic etiology were significantly least likely to receive vaccination.
- Among patients with epilepsy that had been vaccinated for COVID-19, twice as many patients opted for Comirnaty as opposed to Coronavac.
- The administration of COVID-19 vaccines in patients with epilepsy was not found to have a significantly increased rate of AEFI.

According to the Drug Office of the Department of Health, The Government of Hong Kong SAR, periodic updates on monitoring COVID-19 vaccination suggested that 13.5 million doses of vaccines had been given and 6.07 million people had at least one dose of vaccination as of 6 March 2022 (representing a vaccine uptake of 88% in the general public). The expert committee on clinical events assessment following COVID-19 immunization gave timely information regarding any untoward effects of immunization. 7042 reports of adverse events were reported so far, constituting 0.06% of total vaccine doses. There were 67 cases of death within 14 days of vaccination (0.0005% of doses) and none were deemed to be associated with vaccination (either causally or affiliated or pending further assessment).[9]

The vaccination fact sheet for Sinovac (version dated 14/2/22) suggested that the vaccine should not be given to persons with "severe neurological conditions" or "uncontrolled severe chronic diseases." In addition, in the column designated *Precautions*, it was said that "for patients with... history of convulsions, epilepsy...the vaccine should be used with caution."[10] These wordings may, and understandably will, cause reasons of concern for patients with epilepsy and their family.

Our current study has the pre-study objective of setting out the general scene of vaccination with a view to understanding the difficulties with which healthcare professionals face in the promulgation of COVID-19 vaccination.

2 | METHODS

This is a cross-sectional study to investigate the patterns of vaccination among patients with epilepsy aged 18 years or above, 12 months after the territory-wide vaccination program was made available in Hong Kong, in the setting of a regional hospital (also a tertiary referral center for epilepsy). We examined the basic demographics (including allergy to antiseizure medications), the choice of vaccine, any vaccine-related worsening of seizures, status epilepticus, worsening of etiologies of epilepsy and adverse events following immunization (AEFI) based on electronic records at points of contact (ie, medical consultations), any documented evidence of full discussion on nature, effect and adverse effects of vaccination. The seizure types, etiology and epilepsy types were classified according to the guidelines by the International League Against Epilepsy (ILAE). The AEFI (including the time frame of such connotations) was defined according to the guidelines set out by the Department of Health, Hong Kong SAR (please refer to Appendix A). Patients who have had follow-up at the hospital of enquiry in the previous 4 months were the subjects of confidential study. Data was analyzed by means of statistical softwares for qualitative and quantitative analysis (SPSS28.1, python statistical packages). Data access dates were 22/2/22–5/3/22.

With the ambit of the current study, the aim of examining AEFI would be to uncover any unreasonably high rate of events. The statistics from the Centre of Health Protection (CHP) revealed a nominal rate of AEFI at 0.06% among all delivered doses of COVID-19 vaccines. Hence, a sample size of 200 may detect an unusual rate of AEFI that is 8.3 times the baseline risk in the population vaccinated. Our current study is a cross-sectional study which aims at collecting data swiftly within a short space of time under limited resources and therefore we may put into perspective the risk stratification which may be envisaged with the given constraints.

3 | RESULTS

3.1 | Demographics

A total of 200 patients whose anonymized data were analyzed formed the basis of the current cross-sectional study. 49.5% were females and the mean age was 45 years. Focal epilepsy constituted the majority of the cohort (75%, 150/200) whereas generalized epilepsy constituted 25% (50/200). The etiologies according to International League Against Epilepsy (ILAE) classification of seizures[11] showed that the most common category was the structural cause (34%), followed by cryptogenic (29%), genetic (19%), immune (7%), metabolic (6.5%), and infectious causes (4%). In all, 150 patients had focal aware, focal impaired awareness or focal to bilateral tonic–clonic seizures. In all, 50 patients had generalized seizures, including those with motor and non-motor onset. Allergy to antiseizure medications (any one of the following 15 agents: phenytoin, phenobarbitone, carbamazepine, oxcarbazepine, sodium valproate, levetiracetam, lamotrigine, lacosamide, topiramate, perampanel, brivaracetam, rufiniamide, gabapentin, pregabalin, and zonisamide) was common at 11%. The proportion of refractory epilepsy defined by the Taskforce on refractory epilepsy by ILAE[11] was 47.5%, reflecting the nature of a cohort that was affiliated to a tertiary referral center and hence a higher rate of refractory epilepsy. Elderly age (defined as 65 years or above) constituted 16%(32/200). Detailed discussion on the nature, effect, risk including rare but serious side effects and the option of no vaccination was documented in 6.5%(13/200).

3.2 | Patterns of vaccination

The overall uptake of COVID-19 vaccines among this cohort was 51.5%(103/200). The total number of vaccines doses delivered to our cohort of patients was 214. When compared with the general population in Hong Kong (6.07 million vaccinated as of 6/3/22, an uptake rate of 88%), the rate of uptake of vaccination in our patients with epilepsy is 59% of that of the general population.

The number of patients having received the BioNTech vaccine(71, 69%) was more than twice that of patients receiving the Sinovac vaccine(35, 34%). In all, 59 and 7 patients received 2 and 3 doses of the BioNTech vaccine, respectively. In all, 27 and 4 patients received 2 and 3 doses of the Sinovac vaccine, respectively. Of interest, 3 patients received 2 Sinovac vaccines followed by 1 BioNTech vaccine (ie, mixed vaccination) (Table 1). The percentage of patients who have kept up-to-date with all currently available doses of vaccination was merely 7% (14/200).

The uptake of COVID-19 vaccines was highest among patients with cryptogenic or metabolic etiologies (both 69%) and lowest with a genetic etiology (34%). Those with allergy to antiseizure medications, refractory epilepsy and those of elderly age had a slightly lower vaccination rate, at 45%, 49.2%, and 46.9%, respectively. Major discussion on vaccination was documented in 6% of patients (Table 2). Statistical analysis with the correlation between demographics and vaccination showed that the cryptogenic category and the genetic etiology were associated with vaccination ($P = .002$) and non-vaccination ($P = .02$), respectively (one-way ANOVA).

3.3 | Reasons for non-vaccination

The reasons for non-vaccination (n = 97) are, for the majority, due to personal preference (92/97 = 95%). This may be either confirmed after direct discussion with medical staff (7/97 = 7.2%) or presumed as no other coexisting legitimate reason could be found (eg, alleged concurrent use of new oral anticoagulant) (85/97 = 87.8%). In all, 3% of those non-vaccinated are due to mental incapacity (3/97) and one patient could not receive vaccination due to recent clinical COVID-19 infection (1/97). Another patient had a legitimate reason for non-vaccination, namely concurrent cancer chemotherapy (1/97). The demographics of those who did not receive vaccination can be inferred from Table 2.

TABLE 1 Vaccination pattern among all doses of vaccines delivered

Number of patients receiving BioNTech = 71
1 dose = 5
2 doses = 59
3 doses = 7
Number of patients receiving Sinovac = 35
1 dose = 4
2 doses = 27
3 doses = 4
Number of patients receiving 2 doses of Sinovac + 1 dose of BioNTech
No. = 3

3.4 | Side effects related to COVID-19 vaccines

Worsening of seizures in the 14-day period following vaccination (all BioNTech) was observed only in 3 patients (1.5%), constituting an event rate of 1.4% of all delivered doses within this cohort. All three patients had generalized epilepsy with a genetic etiology. One patient had concurrent genetic etiology with an allergy to antiseizure medications. One patient had genetic etiology together with refractory epilepsy. There was no patient suffering from vaccine related hospital admissions, status epilepticus, serious allergy, worsening of the underlying etiology of epilepsy, death, or other categories designated under AEFI. We have detailed below the three cases in which alleged worsening of seizures occurred.

The rationale for putting a seizure 2 weeks after vaccination in connection was based on the definition of adverse events following immunization (AEFI) set out by the Department of Health of our government. In this regard, the seizure can be considered "an unusual event that is thought by health workers or the public to be related to immunization." The association did not suggest causation per se but for the purpose of reporting public health statistics, we will use the definition of AEFI.

3.5 | Case 1

A 25-year-old office assistant gave a history of idiopathic generalized epilepsy with electroencephalogram showing generalized spike and wave discharges (presumed

TABLE 2 Demographics and vaccination uptake of patients with epilepsy

	N (% of cohort)	Number vaccinated (% of category)	Worsening of seizures
Focal aware, focal impaired awareness or focal to tonic–clonic seizures	150 (75%)	81 (54%)	0
Generalized seizures including motor or nonmotor onset	50 (25%)	22 (44%)	3
Structural	68 (34%)	32 (47%)	0
Cryptogenic	58 (29%)	40 (69%)	0
Genetic	38 (19%)	13 (34%)	3
Immune	14 (7%)	6 (42.8%)	0
Metabolic (and drugs)	13 (6.5%)	9 (69%)	0
Infectious	8 (4%)	3 (37.5%)	0
Allergy to antiseizure medications	22 (11%)	10 (45%)	1
Refractory epilepsy	95 (47.5%)	42 (44.2%)	1
Elderly age (≥65 y)	32 (16%)	15 (46.9%)	0
Discussion on vaccination	13 (6%)	4 (30.7%)	0

genetic). With sodium valproate and levetiracetam, the prevailing seizure frequency of the patient was between 0.25 and 1 per month (the patient had his last seizure 1 month before his second dose of BioNTech vaccination). He had an afebrile seizure within 2 weeks of his second dose of BioNTech vaccination. The next seizure was 3 months afterwards. There was no hospitalization as a result of the episode and the patient went on to have a third dose of BioNTech 6 months later.

3.6 | Case 2

A 33-year-old epilepsy patient with mitochondrial disease and moderate intellectual disability had no seizure for 7 months prior to the date of the 2nd BioNTech vaccination while on lamotrigine 50 mg bd, folic acid 5 mg daily and ubidecarenone 300 mg bd. It was reported that the patient developed two seizures (in clusters) on the day of the 2nd BioNTech vaccination with a low grade fever. The seizures did not result in hospitalization and the patient suffered no major sequelae from the episode. Panadol mitigated the fever. The patient did not have any further seizure afterwards.

3.7 | Case 3

A 36-year-old lady with epilepsy onset aged 5 and generalized absence epilepsy had her last seizure in Aug 2020. After her second dose of BioNTech injection in Aug 2021 she had a transient episode of loss of consciousness, followed by fever. The episode was clarified with her carers to be a seizure. The seizure did not result in hospitalization and the patient remained seizure free afterwards.

The following observations can be made from the results of our study:

1. The vaccine uptake among patients with epilepsy is approximately 60% of the general public 1 year after the inception of the vaccination program in Hong Kong.
2. Approximately twice as many patients with epilepsy who received COVID-19 vaccination chose BioNTech as opposed to Sinovac.
3. The proportion of patients with epilepsy who can keep up-to-date with all available doses of vaccines was merely 7% (ie, 3 doses of BioNTech or Sinovac, or 2 doses of Sinovac plus 1 dose of BioNTech).
4. Patients with epilepsy with genetic etiology are least likely to receive COVID-19 vaccination.
5. Our study showed prima facie evidence that there was no unreasonably high rate of unacceptable side effects after vaccination among patients with epilepsy, whether with BioNTech or Sinovac.
6. Patients who developed transient worsening of seizures had received BioNTech vaccine. No case was reported with Sinovac vaccine.
7. Refractory epilepsy, allergy to antiseizure medications, and elderly age (> = 65) did not confer a different vaccination pattern, nor did they bring about any unusually high rate of AEFI.

4 | DISCUSSION

While the rate of uptake of COVID-19 vaccine is not the most important piece of information, as it is expected to increase with time, the pattern of vaccination may illuminate the facilitators and hurdles toward vaccine uptake, more specifically in our susceptible category of patients with epilepsy. Explaining the facts, engaging doctors' advice, enlisting support from epilepsy nurses, and understanding the difficulty with patients and family's perception on risk and benefit can all help increase the uptake of vaccination in our community.

The strength of the current study is that all the patients are uniformly assessed and followed up by specialists. A cross-sectional study rendered a swift picture of the question under scrutiny. This is important when we are dealing with a pandemic that is evolving quickly and having on hand preliminary data to deal with real-life situations is ever more important. The weakness of the current study is understandably its limited sample size, which could have been circumvented with a Clinical Data Analysis and Reporting System (CDARS) search, yielding greater power for analyzing AEFI. Minor side effects are not often reported during consultations and may not be included in our current study design. If the individual receives vaccination outside of Hong Kong (eg, Macau or Mainland China), then the data will also not be captured using our linked record system. We acknowledge that, as the current study in our locality has only covered two types of vaccines, more studies are needed regarding the data on other type of vaccines, eg, the AstraZeneca vaccine ChAdOx1-S, Johnson & Johnson's Janssen COVID-19 vaccine and the Moderna vaccine Spikevax. A study with a larger sample size is also required to understand the risk factors for adverse effects. Our current study only gave descriptive results on the idiopathic/genetic etiology and fever as risk factors for worsening of seizures. We may need a more in-depth exploration of other risk factors for predicting worsening of epilepsy-related adverse effects.

4.1 | Available research in vaccination in patients with epilepsy

Our current study was also corroborated by a recent study of a similar nature in which 178 patients with epilepsy having received either an inactivated vaccine or mRNA vaccine were examined in a cross-sectional analysis. The mean number of seizures before vaccination was 1.62 per month and the mean number after vaccination was 1.64 per month. Their conclusion was that all patients with epilepsy tolerated the vaccines well and that the benefits of the vaccines outweighed the risk of increased seizures after vaccination.[12] A small cohort study indicated that, of 54 epilepsy patients surveyed with first COVID-19 vaccination, 2/3 tolerated the vaccines well and with regards to epilepsy related adverse effects, only one patient reported increased seizure frequency after the vaccination.[7] In another cohort study with 111 patients with epilepsy, the risk of developing epilepsy related side effects was reported at 6.1%, with a relative risk of worsening of seizures estimated at 1.02–1.03. Interestingly, in this latter study one patient had status epilepticus.[8] An Italian cohort study, perhaps one of the largest studies, showed that worsening of seizures after vaccination only occurred in 7.65%, mainly in the 7 days following the vaccine administration and these patients usually had a higher mean number of prevaccine seizure frequency.[13] Regarding the issue of vaccination hesitancy and alleged side effects among patients with genetic etiology, a recent study on Dravet's syndrome suggested that vaccination hesitancy was indeed the case, but the risk of seizure worsening was estimated at 13%, with the authors commenting that reassurance should be given to patients, caregivers as well as health care providers about vaccination among patients with epilepsy.[14] These experiences are, in general, in keeping with our current study that the majority of patients with epilepsy will either tolerate the vaccine very well, or have side effects that are likely to be balanced out by the benefit of protection from COVID-19.

4.2 | Comparison of vaccination data for healthy and other neurological disorders in Hong Kong

An up-to-date website regarding the vaccination data for healthy individuals could be found in the Hong Kong Special Administrative Region (HKSAR)'s website (www.covidvaccine.gov.hk/en/). At the time of the study, the vaccination uptake was 88% and the AEFI rate was 0.06% in the general population. The Expert committee on Clinical Events Assessment Following COVID-19 immunization was a board convened by the Department of Health of Hong Kong to provide independent assessment on the potential causal link between AEFI and COVID-19 vaccination in Hong Kong. As of the time of this paper being drafted, the committee found that "there is no unusual pattern identified so far" regarding AEFI, and "there is no evidence that vaccination increases the risk of death for recipients." In the "Safety monitoring of COVID-19 vaccines in Hong Kong" dated March 31, 2022, a report supplied by the HKSAR, the most frequent AEFI due to Sinovac was chest discomfort, chest pain, facial weakness, dizziness, facial asymmetry, numbness, and palpitation. The most frequent AEFI due to BioNTech was dizziness, chest discomfort, rash, shortness of breath, palpitation, and headache. In the section designated "Specific reports," Bell's palsy, myocarditis/pericarditis, thrombocytopenia/thrombosis with thrombocytopenia syndrome were considered the more onerous AEFIs. Regarding the vaccination data for other neurological disorders, there has not yet been published specific data on the individual neurological entities. We have from the individual product inserts the information that "severe neurological conditions" may be contraindicated with Sinovac but there is no such restriction regarding BioNTech. On the Hong Kong Vaccination Dashboard (Hong Kong Vaccination Dashboard (covidvaccine.gov.hk)), the data presented by HKSAR suggested that death rate due to acute stroke among those patients not being vaccinated was approximately five times that of patients being vaccinated. This suggests that the rate of acute stroke was not in any way higher with the vaccinated population.

4.3 | Action plan

We may use the information from our study to give a clear message to the general public about the vaccination gap among patients with epilepsy. We may delegate discussion and information dissemination to many more healthcare professionals, in different clinical situations, to engage patients and family with the appropriate discussions on COVID-19 vaccinations. We can strengthen the logistic support for patients with epilepsy such as providing vaccination opportunities close to and convenient to patients on the day of medical follow-up. We should actively consider the possibility of outreach vaccination for patients with epilepsy who are hostel residents, and if they lack the capacity to give consent, then as a matter of public health urgency, the patients should be offered best-interest decision meetings involving their family and significant others.

4.4 | Conclusions

A vaccination gap exists among patients with epilepsy in Hong Kong regarding COVID-19 prevention. This applies to both the vaccination rate in general for COVID-19, and the specific vaccination that is required to keep the individual up-to-date with COVID-19 vaccination. There is as yet no evidence to suggest serious adverse events with COVID-19 vaccination among patients with epilepsy. An action plan is needed to help this category of patients to increase their vaccination rate.

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CONFLICT OF INTEREST

None of the authors has any conflict of interest to declare.

ETHICAL APPROVAL

We confirm that we have read the journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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APPENDIX A

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AND THEIR RESPECTIVE TIME FRAME OF REPORTING

Bell's palsy	42 d
Anaphylaxis/anaphylactoid reaction	2 d
Encephalomyelitis	42 d
Encephalopathy	42 d
Guillain Barre syndrome	42 d
Myocarditis/pericarditis	14 d
Sepsis/septicaemia	7 d
Thrombocytopenia/thrombosis thrombocytopenia syndrome	42 d
Toxic shock syndrome	3 d
Transverse myelitis	42 d
Any other severe and unusual events that are thought by health workers or the public to be related to immunization	14 d
Disability when associated with COVID19 vaccine	28 d
Hospitalization when associated with COVID19 vaccine adverse event	14 d
Death when associated with COVID-19 vaccine adverse event	14 d