

ACUTE ENCEPHALOPATHY AFTER BNT162B2 COVID-19 VACCINATION: A CASE REPORT AND LITERATURE REVIEW

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Abstract. Several coronavirus disease-2019 (COVID-19) vaccines have been used to reduce COVID-19 infections, transmissions, hospitalizations, and death. Rare adverse events have been reported after vaccination. We report here the case of a 14-year-old girl who developed acute encephalopathy-like symptoms nine days after receiving the first dose of the BNT162b2 (mRNA) vaccine. She initially experienced high fever, headaches, and drowsiness and then developed generalized tonic-clonic seizures that progressed to status epilepticus. Management included anti-convulsant medication, endotracheal intubation and mechanical ventilation. Work-up revealed a positive antinuclear antibody (ANA) test but she did not meet the criteria for systemic lupus erythematosus (SLE). Her seizures improved with immunosuppressive therapy. She was finally discharged home but had residual memory problems interfering with functioning. The etiology of this patient's condition is unclear but could be autoimmune encephalitis due to her vaccination. We review here the literature for similar cases following mRNA COVID-19 vaccination. Further studies are needed to assess the association between autoimmune disease and mRNA vaccination to determine if there is a significant association and if there is what factors may be significant in that association.

Keywords: encephalopathy, mRNA, BNT162b2, COVID-19 vaccine, SLE

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INTRODUCTION

In December 2019, a viral pneumonia cluster of coronavirus disease-2019 (COVID-19) caused by severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) was reported from Wuhan, the People's Republic of China, and has since spread worldwide (WHO, 2020). On 9 March 2022 there were an estimated 449 million people worldwide who had been infected with COVID-19 and an associated 6 million deaths (Johns Hopkins University of Medicine Coronavirus Resource Center, 2022). On 9 March 2022 the Thailand Department of Disease Control stated 3,088,873 people in Thailand had tested positive for SARS-CoV-2 by reverse transcription polymerase chain reaction (RT-PCR), and 23,438 had died (Department of Disease Control, 2022).

A variety of COVID-19 vaccines have been used worldwide to control infection. The ChAdOx1 nCoV-19 vaccine (known as AstraZeneca; University of Oxford's Jenner Institute/Oxford Vaccine Group, Oxford, United Kingdom), BNT162b2 mRNA vaccine (known as Pfizer; BioNTech, Mainz, Germany), mRNA-1273 vaccine (known as Moderna; National Institute of Allergy and Infectious Diseases, Bethesda, MD, USA) and others have been approved for vaccination in multiple countries (VIPER Group COVID19 Vaccine Tracker Team, 2022). These vaccines have been

shown to reduce COVID-19 infections, transmissions, hospitalizations and deaths in randomized controlled trials as well as real-world effectiveness studies (Lopez Bernal *et al*, 2021; Vasileiou *et al*, 2021; Chagla, 2021; Polack *et al*, 2020; Dagan *et al*, 2021; Menni *et al*, 2021). Thailand initiated a national COVID-19 vaccination program on 28 February 2021. Due to initial vaccine supply shortages, the Public Health Emergency Operation recommended the mix-and-match regimen of CoronaVac (Sinovac vaccine; Sinovac Biotech Ltd, Beijing, People's Republic of China) followed by the ChAdOx1 nCoV-19 vaccine for people aged >18 years since it appeared this combination was more effective against the Delta variant than 2 doses of the ChAdOx1 nCoV-19 vaccine (Public Health Emergency Operation Center, 2021). In August 2021 the Thailand Department of Disease Control began recommending 2 doses of the BNT162b2 vaccine for children aged 12-17 years (Department of Disease Control, 2021).

It is important to identify adverse events of a vaccine. Several adverse events have been reported, such as injection site pain, swelling, redness, fever, headache, myalgia, chills, and arthralgia and unusual side effects, such as encephalitis, myocarditis, embolic stroke, deep vein thrombosis and thrombosis with thrombocytopenia syndrome (Hernández *et al*, 2021; Rosenblum *et al*, 2021)

Neurologic events have been reported following COVID-19 vaccination, such as autoimmune encephalitis, demyelination diseases, Guillain-Barré syndrome (GBS), seizures, and acute encephalopathy but it is unclear if these events were random occurrences or due to the COVID-19 vaccine (Cao and Ren, 2021; Goss *et al*, 2021; Liu *et al*, 2021; Rosenblum *et al*, 2021). We report here the case of acute encephalopathy occurring in a 14-year-old girl 10 days after receiving her first dose of COVID-19 mRNA vaccine (BNT162b2). We review the literature for similar cases.

Ethical considerations

This study was approved by the King Narai Hospital Ethics Review Committee (Approval No. KNH 06/2565).

CASE REPORT

A previously healthy, 14-year-old girl without a history of underlying disease received her first dose of the BNT162b2 vaccine on 18 October 2021. She developed a headache beginning that same evening. On 22 October 2021 she developed a high-grade fever and the headache grew worse. She went to a hospital where she was prescribed amoxicillin, ibuprofen, and acetaminophen. On 27 October 2021, she began to have nausea, vomiting, drowsiness and then had a generalized tonic-clonic seizure. The patient was then taken to a provincial hospital

where in the emergency room (ER) she had a temperature of 38.2°C, a pulse rate of 135 beats per minute and an oxygen saturation on room air of 91%. The patient had two more seizures in the ER without regaining full consciousness between the episodes. Her Glasgow Coma Scale (GCS) score was E1V1M3. She was endotracheally intubated and given intravenous diazepam and phenytoin. A computed tomography scan of her brain was normal. Neither she nor her family members had a history of seizures or autoimmune disease.

A complete blood count from the peripheral blood on in the ER showed a white blood cell (WBC) count of 7,880 cells/mm³ with 82% neutrophils and 12% lymphocytes; a hemoglobin of 10.7 g/dl, a hematocrit of 32.6% and a platelet count of 193,000 cells/mm³. Her serum sodium level was 134 mmol/l and her potassium level was 3.25 mmol/l. Her liver function tests were normal. Cerebrospinal fluid (CSF) analysis showed: no WBC, 100 RBC/mm³, a protein level of 66 mg/dl, a glucose level of 74 mg/dl and a Gram stain that was negative for microorganisms. Her serum glucose level was 172 mg/dl.

The patient was admitted with a diagnosis of encephalopathy and experienced 5 more generalized tonic-clonic seizures on the ward. The patient was treated with intravenous cefotaxime, phenobarbital and midazolam. She did not regain full

consciousness. She was transferred to a tertiary hospital on 28 October 2021. Her GCS score at transfer was E1V1M4.

After transfer, the patient had no further seizures. A repeat lumbar puncture showed no WBC, 100 RBC/mm³ and a CSF glucose of 74 mg/dl with a serum glucose of 172 mg/dl and a normal opening pressure of 36 mmH₂O. At this point, the patient was thought to have either viral or autoimmune encephalopathy. The patient was treated with intravenous methylprednisolone and acyclovir. She gradually improved and was eventually extubated on 30 October 2021.

The blood and CSF cultures showed no growth. She had a positive anti-nuclear antibody (ANA) test with a speckled pattern and a titer of 1:1280, a positive anti-SS-A, and a positive anti-Ro. Anti-thyroglobulin, anti-thyroid peroxidase, anti-dsDNA, anti-Smith and anti-cardiolipin IgG/IgM tests were all negative. Her Westergren erythrocyte sedimentation rate (ESR) was elevated at 108 mm/h. Her C-reactive protein level was elevated at 27.2 mg/l. Magnetic resonance imaging (MRI) of the brain showed limbic encephalitis. Her CSF ANA test was positive.

A diagnosis of systemic lupus erythematosus (SLE) encephalitis was ruled out since she did not meet the 2019 European League against Rheumatism/American College of Rheumatology

criteria for SLE (Aringer *et al*, 2019). A diagnosis of Sjögren syndrome was also ruled out since she did not meet the American-European Consensus Criteria for Sjögren syndrome (Vitali *et al*, 2002).

The patient was given IV methylprednisolone for 5 days and then changed to oral prednisolone, 60 mg/day, and intravenous cyclophosphamide, 720 mg every 2 weeks.

After receiving immunosuppressive therapy, the symptoms rapidly improved. She regained consciousness and speech and was able to follow basic commands. However, she still struggled with short-term memory loss and became agitated from time to time. She was discharged from the tertiary hospital on 16 November 2021. Her hospital course is summarized in Fig 1. At her follow-up on 4 December 2021, the patient could function in all activities independently but continued to have memory loss that affected her studies.

DISCUSSION

Uncommon neurological problems have been reported following COVID-19 vaccination, including tremor, diplopia, dysphonia, facial palsy, Guillain-Barre syndrome, seizures, strokes, transverse myelitis, and acute disseminated encephalomyelitis (ADEM) (Goss *et al*, 2021). Our subject appeared to develop autoimmune encephalopathy after the

COVID-19 vaccination.

Vaccination stimulates pro-inflammatory cytokine expression and T-cell response (Giannotta and Giannotta, 2018; Hervé *et al*, 2019). After immunization, antigens are identified as potential pathogens by pathogen-associated molecular patterns (PAMPs), damage-associated molecular patterns (DAMPs), pattern-recognition receptors (PRRs) and stromal cells (Hervé *et al*, 2019). After activation, the immune system initiates a complex series of innate immune cells (*eg*, phagocytosis) and inflammatory mediators are released: chemokines, cytokines and complement (Hervé *et al*, 2019). Various target gene transcription occurs, resulting in endogenous pyrogens, such as interleukins 1 and 6, tumor necrosis factor-alpha, and prostaglandin-E2, being released into the circulation, mimicking the body reaction to natural infection. Mediators and inflammation products in the circulation can affect other systems, cause a systemic reaction and eventually lead to neuroinflammation in some regions after microglia activation. These reactions rely on immunogenetic and innate immune memory (Hervé *et al*, 2019).

From 1990 to 2010, a total of 1,396 cases of encephalitis after immunization were reported to the Vaccine Adverse Event Reporting System (VAERS) in the United States (Al Qudah *et al*, 2012): hepatitis B vaccine (354 cases), influenza vaccine (208 cases), measles,

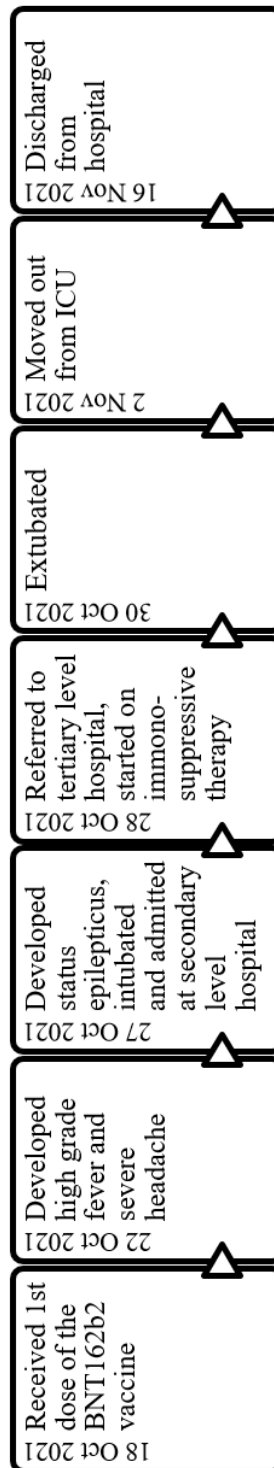


Fig 1 - Study subject hospital course

ICU: intensive care unit

mumps, and rubella vaccine (208 cases) and *Haemophilus influenzae* type B vaccine (120 cases). Seven hundred eight of the above 1,396 cases (50.7%) developed encephalitis within 2 weeks after vaccination (Al Qudah *et al*, 2012), similar to our case.

Encephalitis has been reported after COVID-19 vaccination. Twenty cases of encephalitis out of 110 million doses of the BNT162b2 mRNA vaccine given were reported to the National Institute of Public Health of Québec (INSPQ). This gives an estimated incidence of 2 cases per 10 million doses. Approximately 8 cases of encephalitis per 100 million doses of the ChAdOx1 nCov-19 vaccine were also reported in another study (Zuhorn *et al*, 2021). The incident of encephalitis after COVID-19 vaccination was reported in public access data in the United Kingdom, European Union, and Germany (Table 1). A total of 23 cases of encephalitis have been reported as an adverse event after the administration of BNT162b2 out of 64.6 million doses (Zuhorn *et al*, 2021). We reviewed reported cases of encephalitis after receiving COVID-19 vaccination from various literatures (Table 2). Thirty-two cases were reported to have developed encephalitis after COVID-19 immunization. Twenty cases presented with encephalitis after the mRNA COVID-19 vaccine, 13 patients after BNT162b2, and 7 cases after mRNA-1273.

Our reported case appeared to be a case of autoimmune encephalitis,

meeting the main criteria for this diagnosis: 1) subacute onset of working memory inadequacy and altered mental status, 2) CSF pleocytosis and seizures without a previously known seizure disorder and 3) no reasonable alternative causes (Graus *et al*, 2016).

Some vaccines (*eg*, hepatitis B, human papillomavirus, and measles) have been reported to be associated with new-onset or exacerbation of lupus (Soldevilla *et al*, 2012; de Mattos *et al*, 2021; Agmon-Levin *et al*, 2009; Agmon-Levin *et al*, 2014). One study reported new-onset autoimmune diseases or exacerbation of SLE following mRNA SARS-CoV-2 vaccination (Watad *et al*, 2021). It has been theorized that SARS-CoV-2 mRNA vaccination induces type I interferon (INF) that plays a role in host antiviral activity and cytokine release in SLE pathogenesis (Teijaro and Farber, 2021; Stegelmeier *et al*, 2021; Tang *et al*, 2021).

Three cases of new-onset SLE occurring after mRNA vaccination (BNT162b2 and mRNA-1273 have been reported. Kreuter *et al* (2022) reported a 79-year-old German man who developed malaise and fatigue with a widespread annular, papulosquamous rash located on the trunk and legs. These manifestations occurred 10 days after the reported patient received his first dose of the mRNA BNT162b2 vaccine. A skin biopsy revealed characteristic features of subacute cutaneous lupus erythematosus. A laboratory finding showed positive results for

Table 1
Reported cases of encephalopathy after COVID-19 vaccination

Study period	Vaccine	Number of doses	Number of encephalitis cases	References
4 January-16 June 2021	ChAdOx1 nCov-19		32 cases	https://www.gov.uk
		24.5 million (1 st dose)	7 cases (viral)	
		19.6 million (2 nd dose)	1 case (Bickerstaff's)	
			1 case (limbic)	
	BNT162b2		4 cases (non-infective)	
		16.8 million (1 st dose)	12 cases	
		10.9 million (2 nd dose)	3 cases (viral)	
			1 case (autoimmune)	
			1 case (limbic)	
29 January-10 June 2021	ChAdOx1 nCov-19	46 million	33 cases	https://www.ema.europa.eu
			10 cases (ADEM)	
27 December 2020-31 May 2021	ChAdOx1 nCov-19	9.2 million	8 cases	https://www.pei.de
			5 cases	
	BNT162b2	36.9 million	5 cases	
	mRNA-1273	4.0 million	N/A	

Note: This Table was modified from Zuhorn *et al.*, 2021.
ADEM: acute disseminated encephalomyelitis; N/A: No report available

Table 2
Summary of post-COVID-19 vaccination encephalitis cases from case reports

Country	Age in years	Sex	Vaccine	Dose	Onset	Non-neurological complication	Neurological complication	Treatment	Results	Diagnosis	Reference
Bangladesh	77	M	mRNA-1273	1 st	2 days after vaccination	High grade fever, upper abdominal tenderness	Unconsciousness	Antibiotics, anticoagulant, immunosuppressive therapy	Full recovery	NSTEMI; encephalopathy	Barsha <i>et al</i> , 2021
Germany	21	F	ChAdOx1 nCov-19	1 st	5 days after vaccination	Fever and malaise	Attention and concentration difficulties	Immunosuppressive therapy	Full recovery	Auto-immune encephalitis	Zuhorn <i>et al</i> , 2021
Germany	63	F	ChAdOx1 nCov-19	1 st	6 days after vaccination	Deep vein thrombosis (2 days after vaccination)	Gait deterioration, vigilance disorder, immobilizing opsoclonus-myoclonus syndrome	Broad anti-infective therapy, immunosuppressive therapy	Low-grade tremor persisted	Auto-immune encephalitis	Zuhorn <i>et al</i> , 2021
Germany	63	M	ChAdOx1 nCov-19	1 st	8 days after vaccination	Fever	Aphasia	Rejected treatment	Full recovery	Auto-immune encephalitis	Zuhorn <i>et al</i> , 2021

Table 2 (cont)

Country	Age in years	Sex	Vaccine	Dose	Onset	Non-neurological complication	Neurological complication	Treatment	Results	Diagnosis	Reference
Italy	56	F	BNT162b2	1 st	14 days after vaccination	Malaise and chills	Unsteadiness of gait on the left side, clumsiness of the left arm	Immuno-suppressive therapy	Mild dysmetria, intention tremor of the left upper limb	Encephalomyelitis	Vogrig <i>et al</i> , 2021
Italy	77	M	ChAdOx1 nCov-19	1 st	1 day after vaccination	Fever	Confusion, delirium	Immuno-suppressive therapy	Full recovery	Reversible encephalopathy	Baldelli <i>et al</i> , 2021
Poland	19	F	mRNA-1273	1 st	14 days	Fever, back and neck pain, N/V, urinary retention	Severe headache, nuchal rigidity; bilateral Babinski signs	Immuno-suppressive therapy, therapeutic plasma exchange (TPE)	Mild headache	ADEM	Kania <i>et al</i> , 2021
Qatar	32	M	mRNA-1273	1 st	2 days after vaccination	N/A	Confusion, memory disturbances, auditory hallucination, altered behavior	Antibiotics, antiviral, immunosuppressive therapy	Full recovery	Acute hyperactive encephalopathy	Al-Mashdali <i>et al</i> , 2021

Table 2 (cont)

Country	Age in years	Sex	Vaccine	Dose	Onset	Non-neurological complication	Neurological complication	Treatment	Results	Diagnosis	Reference
Turkey	46	F	CoronaVac	1 st	30 days after vaccination	N/A	Tonic-clonic seizure	Immuno-suppressive therapy	Fully recovery	Encephalomyelitis	Ozgen <i>et al</i> , 2021
USA	77	M	mRNA-1273	1 st	1 day after vaccination	Confusion, fever, rash	Intermittent and irregular orofacial movements, bilateral upper extremity myoclonus	Antibiotics, antiviral, immuno-suppressive therapy	Full recovery	Aseptic meningoen-cephalitis, Sweet syndrome	Torrealba-Acosta <i>et al</i> , 2021
USA	73	M	mRNA-1273	1 st	7 days after vaccination	N/A	Staring episodes, restlessness, and unresponsiveness	Immuno-suppressive therapy, anti-convulsants	Full recovery	Non-convulsive status epilepticus	Liu <i>et al</i> , 2021
USA	86	F	mRNA-1273	1 st	7 days after vaccination	N/A	Acute confusion, visual hallucinations, left frontal headache	Antibiotics, immuno-suppressive therapy	Full recovery	Encephalopathy	Liu <i>et al</i> , 2021

Table 2 (cont)

Country	Age in years	Sex	Vaccine	Dose	Onset	Non-neurological complication	Neurological complication	Treatment	Results	Diagnosis	Reference
USA	22-86 (min- (n=16) max) M (n=5)	F	ChAdOx1 nCov-19	1 st	Median (n=8) 11 days after vaccination	N/A	N/A	Immuno-suppressive therapy	Full recovery	Auto-immune encephalitis	Kaulen <i>et al</i> , 2022
				BNT162b2							
				1 st (n=7) 2 nd (n=5)							
				mRNA-1273							
				1 st (n=1)							

ADEM: acute disseminated encephalomyelitis; F: female; M: male; max: maximum; min: minimum; N/A: not available; N/V: nausea and vomiting; NSTEMI: non-ST segment elevation myocardial infarction; STEMI: ST-elevation myocardial infarction; USA: United States of America

ANA with a titer of 1:320, anti-Ro/SSA and anti-La/SSB antibodies, and the presence of rheumatoid factor. The patient was treated with hydroxychloroquine and systemic corticosteroids. All the skin manifestations were resolved within 4 weeks. Gambicher *et al* (2021) reported a 74-year-old German woman who developed erythematous, partly violaceous coalescing macules and papules located on the trunk and extremities occurring 1 day after her first dose of the BNT162b2 vaccine. Laboratory results showed a positive ANA test with a titer of 1:640 having a speckled pattern and having anti-Ro/SSA and anti-La/SSB antibodies. The patient was diagnosed with Rowell syndrome. She was treated with a tapering course of systemic corticosteroids and recovered completely. Báez-Negrón and Vilá (2022) reported a 27-year-old Puerto Rican woman who developed bilateral symmetric polyarthralgia involving the proximal interphalangeal (PIP) joints, metacarpophalangeal (MCP) joints, and prolonged morning stiffness occurring 2 weeks after the second dose

of the mRNA-1273 vaccine. Laboratory investigations showed a positive result for ANA with a titer of 1:160 having a speckled pattern and having anti-Ro, anti-La, and anti-dsDNA antibodies. After treatment with hydroxychloroquine and prednisolone, the rash subsided within a few weeks. However, her systematic symptoms worsened and her dose of prednisolone was increased and she was started on mycophenolate mofetil. Two months later her symptoms resolved and she has had no recurrence after finishing her medicine.

In our case study reported here, it is possible the BNT162b2 mRNA vaccine triggered an autoimmune response that resulted in her encephalopathy. Further studies are needed to determine if the BNT162b2 vaccine can trigger autoimmune encephalopathy and if there are factors that increase the risk that could identify these at-risk subjects prior to vaccination in order to reduce the occurrence of this condition.

In conclusion, we reported here the case of acute encephalopathy following the COVID-19 BNT162b2 mRNA vaccine. The subject responded rapidly to corticosteroid therapy. This unfortunate reaction is rare and the benefits of the vaccine far outweigh the small risk of this reaction. If symptoms do begin to occur, rapid treatment with corticosteroids should be able to mitigate this reaction.

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CONFLICT OF INTEREST DISCLOSURE

The authors declare no conflict of interest.

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