Recrudescence of severe polyneuropathy after receiving Pfizer-BioNTech COVID-19 vaccine in a patient with a history of eosinophilic granulomatosis with polyangiitis

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SUMMARY

A middle age man with a history of diabetes mellitus type 2, hypertension, migraine and eosinophilic granulomatosis with polyangiitis (EGPA) with polyneuropathy in remission presented with paresthesia and motor weakness soon after receiving the Pfizer-BioNTech COVID-19 messanger RNA (mRNA) vaccine. The patient had polyneuropathy 10 years ago secondary to EGPA, which had resolved. EGPA was diagnosed on the basis of typical symptoms and positive sural nerve biopsy. Five days after receiving the first dose of COVID-19 vaccine, he developed heaviness and reduced dexterity of both the upper extremities, which progressed to patchy and asymmetric motor weakness of all four extremities. Given the lack of clear alternative explanation after a thorough work up, recrudescence of underlying asymptomatic polyneuropathy due to a possible reaction to COVID-19 mRNA vaccine was considered although a temporal association with vaccine dose does not prove causality. He was treated with corticosteroids with slow improvement of his symptoms.

BACKGROUND

The current COVID-19 pandemic caused by SARS-CoV-2 has upended the way of life as we know it. In the USA alone, there have been more than 80 million cases with more than 700 000 deaths to date.[1] Besides the significant illness-related morbidity and mortality, there has been huge financial impact all over the word. Tremendous efforts have been made globally to develop vaccines effective against COVID-19. In the USA, this has been achieved through operation Warp speed, a partnership between various governmental/regulatory and private entities, that oversaw the accelerated development and manufacturing of COVID-19 vaccines.[2] This led to rapid development and subsequent emergency use authorisation (EUA) of the two messanger RNA (mRNA) vaccines (Pfizer and Moderna) and one viral vector vaccine (Johnson & Johnson Janssen).[3–5] Subsequently, Pfizer-BioNTech mRNA COVID-19 vaccine received full Food and Drug Administration (FDA) approval for individuals 16 years of age and older.[6] The trial data for both mRNA vaccines have shown more than 90% efficacy without significant safety concerns.[7 8] Our case suggests a possible need for closer monitoring of people receiving COVID 19 mRNA vaccines with underlying autoimmune conditions and/or polyneuropathy

CASE PRESENTATION

A middle age male physician and first-line healthcare provider with a history of diabetes mellitus type 2, hypertension, migraine and eosinophilic granulomatosis with polyangiitis (EGPA) presented with paresthesia and motor weakness in all four extremities. He had been diagnosed with EGPA associated with polyneuropathy 10 years ago. At the time, he had a classic presentation of new-onset asthma, rhinosinusitis, rash and polyneuropathy. Sural nerve biopsy had findings suggestive of vasculitis. He was treated with mycophenolate mofetil for 2 years and glucocorticoids for 3 years. He had been in remission and off any treatment for vasculitis or neuropathy for past 7 years. At baseline, the patient is physically active and did not have any neuropathic symptoms except for mild sensitivity to cold in the left forearm. He was taking linagliptin/metformin XR, losartan, hydrochlorothiazide, rosuvastatin and pregabalin (for migraine prophylaxis).

The day after receiving the first dose of COVID-19 vaccine (Pfizer-BioNTech), he developed a severe influenza-like illness with temperature of 101°F and body aches. On third day, he went to emergency room, where tests for COVID-19 PCR and influenza were negative. He had mild leucocytosis at 10.24×10^9/L (3.98×10^9/L to 9.57 k/uL) and the eosinophil count slightly increased to 0.94 k/uL (0.00 k/uL to 0.50 k/uL). The Influenza-like symptoms resolved over the next day. However, on day 5 postvaccination, he noticed symmetric heaviness and tiredness of both forearms. He also had associated clumsiness of both hands with reduced dexterity. The repeat lab tests at his primary care physicians office revealed normalisation of white cell count and eosinophil count. Erythrocyte sedimentaion rate (ESR) and C reactive protein (CRP) were normal. Antineutrophil antibody (ANA) and antineutrophilic cytoplasmic antibody (ANCA) were negative. Over the next week, his symptoms continued to worsen. His exertional capacity had a significant decline. On day 12 postvaccination, he noticed weakness of the left side of body. At this point, he was admitted to the hospital. His neurological examination revealed asymmetric findings. Motor strength of right side was 5-/5 for deltoid and hip muscles (adductors and abductors). Motor

Table 1 Laboratory tests on presentation

Test	Result	Laboratory reference range
WBC	9.74	3.98–9.57×10^9/L H
RBC	6.71	4.20–5.60 M/uL H
HGB	14.7	13.0–17.0 g/dL
HCT	47.4	39.0%–51.0%
Platelet count	312	130–400×10^9/L
Glucose	144	70–100 mg/dL H
BUN	15	9–21 mg/dL
Creatinine	1.12	0.72–1.25 mg/dL
Sodium	141	135–145 mmol/L
Potassium	3.2	3.5–5.0 mmol/L L
Chloride	100	98–110 mmol/L
CO_2	28	21–29 mmol/L
Total protein	7.5	6.0–8.3 g/dL
Albumin	4.2	3.3–5.0 g/dL
Globulins	3.3	2.3–3.5 g/dL
Calcium	9.6	8.4–10.2 mg/dL
Alkaline phosphatase	9	53–128 U/L
Bilirubin, total	0.5	0.2–1.2 mg/dL
AST	27	5–34 U/L
ALT	39	0–55 U/L
HbA1C (%)	7.8	4.0–6.0
CSF studies		
White cell count	2	0–5/mm^3
Glucose	90	40–90 mg/dL
Protein	31	15–40 mg/dL

ALT, alanine aminotransferase; AST, asparatate aminotransferase; BUN, blood urea nitrogen; CSF, cerebrospinal fluid; HbA1C, haemoglobin A1c; HBG, haemoglobin; HCT, hematocrit; RBC, red blood cells; WBC, white blood cells.

strength on left side ranged from 4/5 to 5/5 in deltoid, triceps, hip muscles (flexors, adductors and abductors) and ankle muscles (dorsiflexors and planter flexors). Left pectoral and both ankle reflexes were absent. He also had reduced pin prick sensation in an asymmetric pattern (bilateral anterior thighs and left medial calf). The rest of the physical examination was unremarkable. Laboratories revealed normal complete blood count, comprehensive metabolic panel, urine analysis, ESR and CRP. ANA and ANCA remained negative. Haemoglobin A1c (HbA1c) was 7.8% (6.8% 6 months ago). MRI of lumbar and thoracic spine was unremarkable. Cerebrospinal fluid (CSF) studies were normal (red blood cell 0/mm^3, white blood cells 0.002×10^9/L, protein 31 mg/dL). Details of labs and work up are outlined in (tables 1 and 2). Due to concern for immune-mediated recrudescence of polyneuropathy, the patient was started on pulse dose steroids with solumedrol 1 g/day intravenously for 3 days with some improvement in strength and reappearance of both ankle reflexes. He was discharged on 1 mg/kg prednisone daily to follow-up with neuromuscular specialist for nerve conduction velocity (NCV)/electromyography (EMG) studies. However, 3 days later, the patient presented to emergency department (ED) again with blurring of vision in both eyes and worsening weakness of left upper and lower extremities. He was evaluated by neurology, which confirmed worsening of strength of his left upper and lower extremity similar to the hospital admission few days ago. Vision in both eyes was noted to be 20/50 (baseline 20/20) without any visual field deficits. MRI of the brain and orbit was unremarkable. Blurring of vision was thought to be secondary to lens oedema due to glucocorticoids and fluctuations in blood sugars. He received another dose of 1 g solumedrol and was discharged to follow-up with outpatient neurologist to get NCV/EMG. He was seen by a retina specialist and eye examination was unremarkable with no evidence of optic neuritis or vasculitis. Over the next couple of days, patient started having significant neuropathic pain in the left arm, forearm and thighs. Follow-up with the neurologist revealed similar asymmetric motor weakness same as the recent ED visit along with new finding of mild left foot drop.

INVESTIGATIONS

- MRI of the brain, orbits and spine (cervical, thoracic and lumbar) was unremarkable.
- NCV/EMG was suggestive of mild chronic denervation in the left upper and lower extremities but no acute findings.

DIFFERENTIAL DIAGNOSIS

EGPA relapse

At the time of initial EGPA diagnosis, patients' neurological symptoms had some similarities with current symptoms, that is, heaviness of both arms with loss of dexterity, followed by motor weakness and pain. However, there were some notable differences such as weakness and paresthesia were symmetric with a monophasic pattern unlike the asymmetry and fluctuations noted at this presentation. Also, left foot drop is a new finding this time. Second, at the time of original diagnosis, patient had associated symptoms of rhinosinusitis over months, new-onset asthma and maculopapular rash on palms, which were not present this time. Given differences in pattern of symptoms, lack of other associated symptoms and unremarkable laboratory studies (normal or near-normal eosinophils, ESR, CRP and negative ANCA), EGPA relapse was deemed unlikely.

Guillain-Barre syndrome

The patient's clinical picture that started as paresthesia and progressed to asymmetric patchy motor weakness did not fit Guillain-Barre syndrome (GBS). CSF studies and MRI of the spinal cord were unremarkable. Moreover, patient responded to steroids.

Diabetic mononeuropathy multiplex

Mononeuropathy multiplex has been described in the literature as a rare and atypical complication of diabetes. There are a few case reports describing this condition. It is usually seen in patients with mildly elevated HbA1c and has a subacute onset. Electrodiagnostic studies are usually abnormal and suggestive of axonal degeneration.[9] Rapid onset of symptoms and unremarkable NCV/EMB made diabetic mononeuropathy multiplex less likely.

Final diagnosis

Given the close temporal relationship after receiving the first dose of COVID-19 Pfizer-BioNTech mRNA vaccine and lack of alternative explanation it was concluded that this patient likely had a reaction to Pfizer-BioNTech mRNA vaccine leading to recrudescence of underlying asymptomatic polyneuropathy.

TREATMENT

Following the pulse dose steroids in hospital, patient remained in 1 mg/kg prednisone daily for 2 weeks. After follow-up with neurologist, prednisone dose was tapered every 5–7 days until a 10 mg/day dose was reached and then slowly tapered off over next 5 months.

Table 2 Additional laboratory studies

Lab test	Results prior to presentation	Results on presentation	Result on follow-up	Laboratory reference range
CK		70		30–200 U/L
Sedimentation rate (ESR)	1	14	2	0–25 mm/hr
CRP	0.5 (1–3 mg/L)	CRP <0.20		≤0.49 mg/dL
Anti-neutrophil cytoplasmic Ab, IgG	Negative	Negative		
Anti-nuclear antibody	<1:10	<1:40		<1:40
C3	165		114	82–193 mg/dL
C4	46		38	15–57 mg/dL
Beta-2 glycoprotein 1, IgG		0		0–20 SGU
Beta-2 glycoprotein 1, IgM		1		0–20 SMU
DNA (Ds) antibody DNA		Negative	Negative	
SSA		1	<1.0	0–40 AU/mL
SSB		0	<1.0	0–40 AU/mL
Rheumatoid factor		<13.0	<14	≤30.0 IU/mL
Cryoglobulin, qualitative		Negative		
Vitamin B12		268		213–816 pg/mL
Methylmalonic acid		0.24		0.00–0.40 umol/L
HIV 1/2 Ab +HIV 1 Ag		Non-reactive		
Hepatitis C antibody		Non-reactive		
Hepatitis B antigen and core antibody			Negative	
Serum protein electrophoresis		Normal pattern	Normal pattern	
Serum free light chains				
Kappa			9.82 mg/L	3.30–19.40 mg/L
Lambda			5.02 mg/L	5.71–26.30 mg/L
Kappa/lambda ratio			1.96	0.26–1.65
Immunofixation			Normal	
Urine porphyrins random			Within normal limits	
Acetylcholine receptor binding Ab			Negative	
Acetylcholine receptor modulating Ab			Negative	
Striated muscle Ab screen			Negative	
Lyme serology			Negative	
Jo-1			Negative	
Smith			Negative	
SCL-70			Negative	
Ribosomal P			Negative	
COVID-19 IgG			Negative	

CK, creatinine kinase; CRP, C reactive protein; ESR, erythrocyte sedimentation rate; SCL, Topoisomerase 1; SGU, standard IgG beta 2 glycoprotein unit; SMU, Standard IgM beta 2 glycoprotein unit; SSA, Anti Sjogren's syndrome A; SSB, Anti Sjogren's syndrome B.

OUTCOME AND FOLLOW-UP

The patient sought opinions from two different referral centres. He was evaluated by a neuromuscular/neuroimmunologist at a national referral centre via telemedicine and was later seen by another neuromuscular specialist at a local referral centre. A repeat NCV/EMG, done 1 week after the first one, revealed similar results without any signs of progression. It was thought that either the injury was not significant enough to show up on NCV/EMG studies or perhaps it was still too early to see the changes. A nerve biopsy was deferred as it was considered low yield and patient had already undergone sural nerve biopsy on left side which was predominantly affected this time also.

Over the next few months, he had slow improvement in his symptoms and started rehabilitation. His vision and neuropathic pain have improved. He was unable to work for first 2 months following which he returned to work with limited duties. Now 9 months since receiving the vaccine, he continues to make slow recovery with rehabilitation and is performing nearly full duties.

DISCUSSION

Vaccines are among the most effective tools in prevention of infectious diseases. On the other hand, vaccines themselves can be associated with various kinds of adverse reactions, including neurological adverse events like GBS, multiple sclerosis, neuritis and small fibre neuropathy.[7 8] Various pathophysiological theories have been proposed to explain the autoimmune adverse events after receiving vaccines, including molecular mimicry, immune-mediated bystander activation, immune-mediated hypersensitivity to the solvents/adjuvants[10] and inflammatory damage.[11] However, the rarity of such events and variable latency period makes it extremely difficult to ascertain causality and provide an accurate pathophysiological explanation,.[11]

During this unprecedented time of the COVID-19 pandemic, the development and EUA of the vaccines has brought great hope. There were few significant safety concerns during the trials for the two mRNA vaccines. Higher rate of local reactions was noted with both the mRNA

vaccines but were not significant. Incidence of systemic reactions with fatigue, headache and fever (influenza like illness) was also higher in vaccine groups. These were mild with the first dose, but a significant number of participants had more severe systemic reaction after the second dose of both vaccines. There were no significant adverse events, including hypersensitivity reactions with either vaccine.[12 13] Few cases of Bell's were reported during the trials, which were considered to be incidental and not related to vaccines.[14 15] There is lack of safety data in certain populations like pregnant women or immunocompromised patients who were not included in trials. Subgroup data for those with underlying autoimmune conditions who were included in trials are not available. While autoimmune dysregulation is thought to play a role in various complications associated with COVID-19 infection,[16] there have been no confirmed reports of autoimmune or neurological adverse events with COVID-19 mRNA vaccines so far.

The need and importance of vaccines against COVID-19 to help control the current pandemic and reduce incidence of severe illness cannot be emphasised enough. To date, more than 255 million people have received at least one dose of COVID-19 vaccines and greater than 218 million people are fully vaccinated in USA.[17] However, when vaccinating millions of people, emergence of new adverse events not seen during the clinical trials with its fewer patients is not entirely unexpected. Such events require further investigation to determine a relationship to the vaccine versus simply coincidental occurrences. For example, allergic reactions including anaphylaxis and inflammation of the heart (myocarditis and pericarditis) have been found to be adverse events in vaccinated individuals not seen during clinical trials with both the mRNA COVID-19 vaccines.[18–20] Similarly, an increased risk of thrombosis with thrombocytopenia syndrome has been suggested with the use Johnson & Johnson Janssen viral vector vaccine in adult women younger than age 50.[21]

Currently, CDC recommends that people with autoimmune conditions may receive an mRNA COVID-19 vaccine series along with an additional dose 28 days after completing an mRNA COVID-19 vaccine series.[22] Additionally, a booster dose is recommended for a subset of high-risk population who have received Pfizer-BioNTech mRNA COVID-19 vaccine at least 6 months after completing the series.[23]

Our case may represent an isolated occurrence as an individual's personal predisposition, medical history, genetics and environmental factors play a role in their susceptibility to autoimmune reactions. While a temporal relationship with receiving the vaccine may indicate an association, it cannot determine causality without any definitive proof of diagnosis, especially when other possible conditions (eg, EGPA, diabetic neuropathy, etc) can also have similar findings. However, this case perhaps suggests a need of closer monitoring of patients with autoimmune conditions and/or neuropathies receiving COVID-19 mRNA vaccines until more data are available. Both CDC and vaccine companies have reporting systems in place for such events,[24 25] where this case has been reported as well.

Patient's perspective

Being a physician, I have been providing care to hospitalised patients with COVID-19 on daily basis. As pandemic was reaching its peak, the capacity of healthcare services was stretched thin. It became more important than ever that healthcare providers remain available and help out despite the risks. Hence, the decision to get the COVID-19 vaccine was quite straightforward. The recurrence of my neuropathies after getting vaccine was unfortunate and brought back some traumatic memories of a very difficult time in the past. Being unable to perform usual daily activities and inability to work when it was most needed (for months) was quite devastating. Such an illness can also take a huge toll on the loved ones providing care to patients. I feel extremely blessed to have a family that have stood by me with such undying love. I am grateful for the care from my physicians. I am also thankful for my employers for their support during this difficult time. Although I hope for a full recovery in the future, the uncertainty regarding health and ability to fully perform my job is nerve wracking. As a physician and a front-line healthcare provider who wishes for this pandemic to be over soon, I certainly believe in the importance and need of vaccines against COVID-19 despite the adverse reaction that I suffered.

Learning points

- Vaccines can have unintended direct or indirect effects, which should be monitored closely.
- Adverse events after vaccinations require extensive investigation to determine any association and causality.
- Closer monitoring of patients with autoimmune conditions and/or neuropathies may be warranted to rule out any trends until more data are available regarding the use of COVID-19 mRNA vaccines in this population.

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Case reports provide a valuable learning resource for the scientific community and can indicate areas of interest for future research. They should not be used in isolation to guide treatment choices or public health policy.

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