



## Clinical short communication

## Small fiber neuropathy following COVID-19 vaccination: A case series

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## ABSTRACT

Various peripheral neuropathies, from facial palsy to Guillain-Barre Syndrome, following vaccination have been reported in several different vaccination contexts. However, the relation between small fiber neuropathy and vaccination is still unclear. In the context of COVID-19 vaccination it is even more difficult to assess a secure causality due to the short time that has elapsed since the vaccination, thus research on possible pathophysiology is still in progress. Nonetheless, due to the extensive vaccination campaign held for COVID-19 since 2021, we were able to collect and describe clinical and electrophysiological data of 16 patients with suspected small fiber neuropathy following vaccination, of which 9 fulfilled the criteria for diagnosis of SFN.

Defining the causality is arduous, but temporality, analogies with other vaccinations and/or infections support our hypothesis. We underline the importance of post-marketing surveillance to detect rare adverse effects and consequently tailor future studies.

## 1. Introduction

Small Fiber Neuropathy (SFN) refers to damaged unmyelinated or thinly myelinated sensory and/or autonomic fibers. SFN is clinically dominated by neuropathic pain and autonomic complaints, leading to a significant reduction in quality of life [1]. Case definition and diagnosis is still debated as clinical symptoms and signs can be very variable and sometimes they can overlap with those of large fiber involvement (as in mixed large and small fiber neuropathies). On the other hand, assessment of small fiber function cannot be easily done in many centers, as it requires specific testing and expertise [2].

New criteria for research and/or clinical trial purposes have been proposed, including clinically defined SFN in contrast to the “test supported” SFN in order to more easily include patients for future research, avoiding the difficulty of the specific tests.

Therefore, depending on the set of criteria used and the availability of specific small fiber tests, the diagnosis of pure SFN is still primarily based on clinical presentation, with typical symptoms and signs of small fiber involvement and no symptoms and signs of large fiber involvement (i.e., normal vibration and proprioception). Among the different available tests, intraepidermal nerve fiber density has shown sensitivity of 88 % and a specificity of 91 % in the diagnosis of SFN [3].

However, the possible association between previous vaccination and small fiber polyneuropathy is not well defined. We therefore intend to

identify whether a clinical and quantitative relationship between COVID-19 vaccinations and small fiber neuropathy (SFN) exists.

## 2. Methods

We present a case series of 16 patients referred to our Department of Clinical Neurophysiology, Rigshospitalet, Copenhagen, with the suspicion of a Small Fiber Neuropathy related to COVID-19-vaccination. Patients referred in the period January 2021 to February 2023 were included in this case series. The suspicion of a vaccine-related syndrome was defined as symptoms' debut within 30 days after vaccination. All patients  $\geq 18$  years without previous clinical history of SFN were included in the study. All the patients signed informed consent for the study.

## 3. Results

## 3.1. General information

We collected data from 16 patients suspected of Small Fiber Neuropathy after vaccination. General information is resumed in Table 1. Most patients were female (F = 14; M = 2), with age 27–64 y.o. (median 50,1  $\pm$  12,1 years). Patients were vaccinated against COVID-19 with Pfizer BioNTech (BNT162b2), Moderna (mRNA-1273) or Oxford/Astra

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**Table 1**

Demographics and general information of patients. / = no comorbidities; bold = comorbidities that can cause SFN (Small Fiber Neuropathy).

Patients	Gender	Age	Time to onset (days)	Vaccination (Type, dose)	Comorbidities
1	M	64	1	Pfizer, 2nd	Seronegative Rheumatoid Arthritis, Spinal stenosis
2	F	49	7	Astra Zeneca, 1st	/
3	F	64	0	Pfizer, 1st	Osteoporosis, Chronic Pyelonephritis
4	F	64	1	Pfizer, 1st	Dystonia
5	F	60	0	Pfizer, 2nd	/
6	F	51	15	Pfizer, 2nd	Lung sarcoidosis
7	F	61	30	Pfizer, 2nd	/
8	F	37	0	Pfizer, 2nd	ADHD, Tourette, Asthma, Fibromyalgia, Hypothyroidism
9	F	45	7	Pfizer, 2nd	Chronic pain after car accident
10	F	48	7	Pfizer, 1st	/
11	F	28	2	Moderna, 2nd	Sinusitis treated with Bioclauid at the same time of vaccination
12	F	59	7	Pfizer, 1st	Hypothyroidism, interstitial cystitis
13	M	43	5	Pfizer, 2nd	Horton's headache
14	F	57	9	Pfizer, 2nd	Chronic constipation, borderline personality with anxiety
15	F	52	5	Pfizer, 2nd	Previous colon cancer
16	F	27	2	Pfizer, 3rd	/

Zeneca (ChAdOx1-S) vaccines. Time from vaccination to onset of symptoms varied from few hours to 30 days (median  $6.1 \pm 7.6$  days). Two patients (Pt. 1 and 6) had comorbidities that can be linked with SFN – see Table 1.

### 3.2. Clinical findings

88 % of patients described burning/tingling sensation, usually in a length-dependent pattern. One patient (pt. 15) presented with an atypical picture with stiffness in fingers and toes, associated with sensory disturbances. Pt. 16 presented with atypical unilateral symptoms in both upper and lower extremities.

A full neurological examination was performed in all patients. Clinical findings are resumed in Table 2. A normal sensory examination was found in 4 patients (25 %). In 11 patients (69 %) signs of small fiber affection were found, as reduced pain and/or temperature sensibility and/or hyperalgesia. Muscular tonus and force, coordination and gait were normal in all patients. Reflexes were found normal in 13 patients (81 %).

Due to the acute/subacute onset, 5 patients (31 %) were admitted to hospital with the suspicion of Guillain-Barre' Syndrome. Four of them were examined with a lumbar puncture, with CSF found normal.

### 3.3. Electrophysiological findings

All patients underwent an electrophysiological examination for large-fiber polyneuropathy examining at least one sensory (sural nerve-antidromic) and one motor (tibial nerve-belly-tendon) nerve in the LE. All the examinations were done with Dantec® Keypoint® G4 EMG / NCS / EP Workstation (Natus/Dantec, Denmark). Temperature was maintained stable during the examination using a warming lamp ( $>32$  °C). All recordings were done using surface electrodes and surface stimulator.

All the examinations were normal according to normal values for our laboratory. To investigate SFN, patients were studied with quantitative

**Table 2**

Clinical findings: symptoms and signs. UE = upper extremities; LE = lower extremities.

Pt.	Symptoms	Sensory examination	Muscle Tone and Force; Coordination and gait	Reflexes
1	Sleeping/burning sensation distal UE.	Decreased touch, pinprick distal UE.	Normal	Normal
2	Burning sensation distal LE and UE.	Decreased touch, pinprick distal UE.	Normal	Normal
3	Burning sensation distal LE and UE.	Dysesthesia and hyperalgesia left foot.	Normal	Normal
4	Burning sensation distal LE and UE.	Decreased touch, pinprick gloves-sock form.	Normal	Normal
5	Tingling sensation distal LE.	Decreased temperature, pinprick and vibration distal UE.	Normal	Normal
6	Burning/tingling sensation distal LE.	Normal.	Normal	Normal
7	Sleeping/tingling sensation distal LE.	Dysesthesia distal UE.	Normal	Normal
8	Burning pain distal UE.	Decreased temperature and pinprick distal in UE.	Normal	Reduced Patella bilaterally
9	Burning sensation LE and chest.	Decreased temperature, touch, and pinprick in UE.	Normal	Normal
10	Burning sensation distal LE and UE.	Dysesthesia gloves-sock form.	Normal	Normal
11	Burning sensation distal LE and UE.	Normal.	Normal	Normal
12	Burning sensation distal LE and UE and mouth.	Normal.	Normal	Normal
13	Burning sensation distal LE and UE and mouth.	Hyperesthesia distal UE.	Normal	Normal
14	Burning pain distal LE and UE. Cramps and tiredness.	Hyperalgesia and reduced temperature distal UE.	Normal	Normal
15	Stiffness fingers and toes, pain UE.	Normal.	Normal	Areflexia Achilles bilaterally
16	Reduced sensibility and paresthesias left-sided (face, UE, and LE).	Decreased touch, pinprick, and temperature left UE and LE.	Normal	Reduced left patella and Achilles

sweat-test upper and lower extremities, quantitative sensory test, and a cutaneous biopsy for intraepidermal fiber density count (IEFND).

The quantitative sensory testing (QST) assesses warm, cold, heat pain and cold pain thresholds using the Medoc™ device (Medoc™ Thermal Sensory Analyser, TSA-2001, Israel). Thermal thresholds were measured at the dorsum of the foot. Warm and cooling detection thresholds (CDT, WDT) were evaluated with the method of limits, with ramp stimuli of 1 °C/s from 32 °C. Values were compared with the database of age- and sex-matched normative values. Results above the 95th percentile were considered abnormal. [3].

The quantitative sudomotor axon reflex test (QSART) assesses the postganglionic sympathetic cholinergic sudomotor function in the extremities. Acetylcholine 10 % is iontophoresed into the skin to stimulate unmyelinated C-fibers. A standardized collection from the forearm,

proximal leg, distal leg, and foot is used, and sweating is measured and quantified by a sudorometer (Q-sweat, WR Medicals Electronics Co, Stillwater, MN) [4].

Skin biopsies were obtained in the distal region of the leg (10 cm above the lateral malleolus, within the sural nerve territory). Biopsies were taken after local anaesthesia (25 mg lidocaine or 25 mg prilocaine) using a 3 mm disposable punch under sterile technique. The biopsies were fixed in cold fixative for up to 24 h at 4 °C, then kept in a cryoprotective solution for one night, and serially cut with a cryostat in sections of 50 µm thickness. Bright-field immunohistochemistry using anti-PGP 9.5 antibodies in 2 % PLP was performed. Intra epidermal nerve fiber density (IENF) was counted at high magnification in at least three sections per biopsy according to published counting rules (IENF have to cross or originate at the dermal–epidermal junction, and secondary branches and fragments are not counted). The resulting IENF number was then compared to the published normal values using the same method [5]. Values below the 0.05 quantile for the age group and sex were considered reduced.

As previously mentioned, a general consensus for the diagnosis of SFN is yet to be achieved. One of the latest diagnostic criteria [2] include typical clinical presentation and confirmation with IENFD. As those criteria have been used mainly in a research/clinical trial context, we decided to continue using the set of criteria used in our laboratory. Indeed, we are mainly in a clinical context and therefore in our Laboratory we base our set of criteria on a combination of the so-called Besta criteria, proposed by Devigili et al. [3] and the Blackmore Criteria, proposed by Blackmore et al. [6]. We define SFN with the subsequent criteria:

- Positive or negative sensory symptoms, with a length-dependent distribution.
- Objective findings that support a small fiber damage (reduced pinprick/temperature sensibility).
- Abnormal findings in at least two out of the three tests available in our Laboratory: IENFD, QST and Q-Sweat.

The rationale of this lies on the fact that the neurological examination is described by the referring doctor, but not repeated in our department. Therefore, we thought it to be sensible not to rely only on one supporting test but to add one laboratory testing to enhance the sensitivity and specificity of our diagnosis, as sensory symptoms alone are not reliable [3]. Using this set of diagnostic criteria, we were able to diagnose 9 patients with SFN. For comparison, with Blackmore criteria 4 patients would have been classified as definite SFN and 6 as possible SFN. With Besta/Devigili criteria SFN diagnosis would have been given

to 11 patients.

We investigated past clinical history in order to differentiate and exclude patients who could have presented with a SFN for other causes. Results are resumed in Table 3.

#### 4. Discussion

Our case series aims to investigate the possible relationship between small fiber neuropathy and previous vaccination against COVID-19. We described 16 patients investigated for vaccine-related small fiber neuropathy in 25 months' period (jan. 2021-feb 2023). For comparison, in the same period our department performed 652 small fiber studies, being the 0,2 % referred with the suspicion of a vaccine related SFN.

Due to the enormous healthcare issue related to COVID-19 pandemic, an extended vaccination campaign has been held to limit the spread of the virus. Therefore, many different suspected complications and/or adverse effects have been described. Assuring a secure causality between vaccination and adverse effect is tremendously difficult, as many different aspects must be considered. During the prelicensure randomized clinical trials it is possible to assess a vaccine's safety and efficacy profile. However, due to the sample size and the limited duration of follow-up, those trials are unlikely to reliably detect rare events. Therefore, it is fundamental to monitor the real-world vaccination experience through active and passive surveillance. However, in this phase we lack a comparator group, making it even more complex to assess a causality. The Bradford-Hill criteria are frequently used to guide decisions, but apart from temporality, are not essential as we navigate in an observational phase, where the risk of bias is much higher [7]. In our case series, the temporal association between vaccination and onset of symptoms support a possible causal association. Although difficult to confirm, some considerations can be done.

Other single case reports of SFN associated with COVID-19 vaccination have been previously published. In 2021 Waheed et al. described one 57 years-old female with subacute onset of intense burning dysesthesias in the feet, one week after receiving the second dose of Pfizer vaccine [8]. In 2022 Khokhar et al. described a 64-years old female with paroxysmal tingling affecting mainly the feet, debuting three weeks after the third dose of Moderna vaccine [9]. Another Pfizer-related case was described by Schelke et al. in 2022, a 52-years old man developing paresthesia, burning and stabbing pain in the arms, accompanied by orthostatic intolerance and tinnitus after the second dose of vaccination [10]. All these cases were confirmed with decreased IEFND in skin biopsy at the distal leg.

Another observational study published in 2022, investigated neuropathic symptoms with SARS-Cov-2 vaccination, describing 23

**Table 3**

Small Fiber Tests. (Q-sweat, quantitative sweat test; QST: quantitative sensory test; IENFD: intraepidermal nerve fiber density).

Patients	Q-sweat	QST: cold and/or warm threshold foot	IENFD	SFN diagnosis Our criteria	SFN diagnosis Besta Criteria	SFN diagnosis Blackmore criteria
1	Abnormal	Abnormal	Normal	Yes	Yes	Definite
2	Abnormal	Normal	Reduced	Yes	Yes	Probable
3	Normal	Normal	Normal	No	No	No
4	Abnormal	Abnormal	Reduced	Yes	Yes	Definite
5	Abnormal	Abnormal	Normal	Yes	Yes	Definite
6	Abnormal	Normal	Normal	No	No	No
7	Abnormal	Normal	Normal	No	Yes	Probable
8	Abnormal	Normal	Reduced	Yes	Yes	Probable
9	Normal	Abnormal	Normal	Yes	Yes	Probable
10	Normal	Normal	Reduced	No	Yes	No
11	Normal	Normal	Reduced	No	No	No
12	Normal	Normal	Normal	No	No	No
13	Normal	Abnormal	Reduced	Yes	Yes	Probable
14	Abnormal	Normal	Reduced	Yes	Yes	Probable
15	Normal	Normal	Reduced	No	No	No
16	Abnormal	Abnormal	Reduced	Yes	Yes	Definite
Total diagnosis				9	11	6 probable 4 definite

patients with new neuropathic symptoms beginning within 1 month after vaccination. Not all patients were studied for SFN, but among 16 biopsies done, 31 % had diagnostic/subthreshold epidermal neurite densities [11].

Moreover, small fiber neuropathies have been previously described in association with other vaccines (Rubies, Varicella, HPV), with a very similar clinical history, with symptoms' debut within few days from vaccination. A skin biopsy was not performed in all, but the temporality suggested a connection [12].

Explaining the possible pathophysiology is arduous, and different mechanisms have been described, considering both the vaccine per se, or one of its components, such as an adjuvant, as the responsible for this adverse effect through antibodies production. Different studies have been made to investigate this possibility, leading in 2011 to the definition of a syndrome, the ASIA (autoimmune/inflammatory syndrome induced by adjuvants), which is typically linked to metals and other substances used in different medications, vaccinations and implants (e. g. aluminum, prosthetic materials etc.) [13]. A review published in 2023 broadens the ASIA spectrum and investigates the possible association between COVID-19 vaccination and the development of autoimmune syndromes, including small fiber neuropathy [14].

Autoimmunity and molecular mimicry are also investigated in immune-mediated neuropathies. A study published in 2022 investigated the correlation between autoantibodies in COVID-19 and the antiviral humoral responses, showing that the presence of autoantibodies in COVID-19 patients correlated with increased antiviral immune response and inflammatory immune signatures [15]. On the other hand, a study conducted in the United Kingdom showed there is no significant structural similarity between SARS-Cov2 genetic or linear protein structure and human peripheral nerve tissue protein structure, making molecular mimicry unlikely. Nevertheless, pathophysiology could be a sum of multiple mechanisms, therefore all the different possibilities must be considered [16].

Another aspect to consider is that such as for other vaccines, different neurological manifestations have been described after COVID-19 vaccination. In august 2021 Garg et al. published a review of all the adverse effects published to that moment [17]. The most common was headache and the most invalidating and dangerous was cerebral venous thrombosis. Other severe neurological adverse reactions include encephalitis, acute disseminated encephalomyelitis (ADEM), stroke and Guillain-Barre syndrome. Interestingly, proposed pathogenesis of Guillain-Barré syndrome is an autoantibody-mediated immunological damage of peripheral nerves via mechanism of molecular mimicry between structural components of peripheral nerves and the microorganism [17,18].

Interestingly, as for SFN, the same adverse effects have been described with different vaccines, suggesting a common pathway not directly dependent on the specific vaccine.

Finally, many different neurological manifestations (headache, myalgias, stroke, transverse myelitis etc.) have been described in association with COVID infection itself and with the long-COVID syndrome.

A study published in 2021 reported 13 patients with new onset paresthesia after COVID infection, in 6 of which skin biopsy confirmed the presence of a SFN [19]. Other studies have investigated autonomic dysfunction following COVID-19 infection, finding a remarkable association between the infection and autonomic functions, including small fiber neuropathy [20]. A study published in 2022 describes SFN as a relevant sequela of COVID-19 in a small cohort of patients evaluated for peripheral nervous system involvement [21].

As assessing causality is arduous, widespread surveillance and standardized registers should be used in the future to evaluate prevalence, clinical and prognostic impact of neurological complications of COVID-19.

## 5. Conclusion

Even if we are not able to assess with complete sureness the causality between vaccination and new onset SFN, our case series, along with a literature analysis, shows an apparent association between the two events. We therefore underline the importance of the post-authorization surveillance on adverse effects of vaccination.

## CRediT authorship contribution statement

**Giulia Carolina Primicerio:** Writing – original draft, Visualization, Investigation, Formal analysis, Data curation, Conceptualization. **Margrethe B. Bille:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization. **Eva Løbner Lund:** Writing – review & editing, Methodology, Investigation, Data curation. **Steffen Birk:** Writing – review & editing, Validation, Supervision, Project administration, Investigation, Conceptualization.

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