Self-reported Side Effects of SARS-CoV-2 Vaccination

Josef Finsterer[1,*], Danice Hertz[2]

ABSTRACT
SARS-CoV-2 vaccines are often promoted as safe. However, real world data tell a different story. The aim of this study is to investigate the type and frequency of adverse reactions to SARS-CoV-2 vaccination in a randomly selected cohort of unrelated individuals. Adverse reactions to the first/second dose of a SARS-CoV-2 vaccine were recorded using an online reporting system called "Pabbly". Patients were asked via social media to report any symptoms temporarily associated with vaccination. One hundred subjects were enrolled. The mean age was 42.6 years (range: 12–74 years). Ninety-one percent were female. The latency period between vaccination and onset of symptoms ranged from zero to 18 days. The most commonly reported symptoms were tingling/vibration/tremor (79%), numbness (57%), heart problems (53%), muscle weakness/muscle pain (45%), dizziness (44%), headache (44%) and fatigue (43%). Three patients developed small fiber neuropathy. Three patients had COVID-19 prior to vaccination. Of the included subjects, 37% had to be hospitalized. Overall, SARS-CoV-2 vaccination is not without side effects, regardless of the product used. In most cases, the reported side effects were not life-threatening, but one third of study participants experienced serious side effects requiring hospitalization and intensive care. Manufacturers of SARS-CoV-2 vaccines should respond appropriately to reports of adverse reactions associated with SARS-CoV-2 vaccination.

KEYWORDS
SARS-CoV-2; COVID-19; vaccination; adverse reaction; side effect

AUTHOR AFFILIATIONS
[1] Neurology & Neurophysiology Center, Vienna, Austria
[2] Private office, Santa Monica, CA, USA
* Postfach 20, 1180 Vienna, Austria; e-mail: fifigs1@yahoo.de

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INTRODUCTION

Vaccination with SARS-CoV-2 vaccines is generally well tolerated, but in some cases mild or severe adverse reactions may occur (1). These side effects may occur within a few days after vaccination (acute COVID-19 vaccination syndrome (ACVS)) or weeks or months after vaccination (post-acute COVID-19 vaccination syndrome (PACVS)) (2). Although health care workers in most health care systems are required to report such side effects to health authorities, publishing side effects of SARS-CoV-2 vaccinations is contrary to political intentions in many countries. This is because politicians are called upon to overcome the pandemic, and the most widespread strategies implemented are vaccination, testing, social distancing and lockdowns. Since vaccination is promoted to be the best way to control the pandemic, there is an urgent need to have an effective and safe weapon at hand. However, real-world data increasingly suggest that adverse reactions to SARS-CoV-2 vaccination are occurring, which may be a reason why the targeted vaccination rates are not being achieved in many countries. The following cohort study was conducted to investigate in a real-world setting which symptoms occur in vaccinated subjects in temporal relation to vaccination.

METHODS

The data was collected as part of an online survey called "Pabbly". "Pabbly" was created by one of the co-authors who had technical computer skills. The subjects were actively asked via social media to report their side effects of the vaccination to Pabbly. These patients were members of private Facebook groups for those affected by vaccination. The information collected was then retrieved and placed into a spreadsheet format to make it easier to interpret and extract better personal health information. All subjects who provided their individual epidemiological data and completed the questionnaire correctly were included. Patients who provided incomplete or inconclusive individual information were excluded. It was not recorded whether these symptoms resolved spontaneously, persisted, or required therapeutic intervention with partial or complete resolution. The study adhered to the tenets of the Declaration of Helsinki.

RESULTS

A total of 100 participants completed the online survey. Ninety-one percent of the participants were female. The average age of the 97 participants who reported their age, was 42.6 years (range: 12–73 years). In terms of race/ethnicity, 88% were white, 5% Hispanic, 3% African American, 2% Asian, and 1% each Pacific Islander and Alaskan Native respectively (Figure 1). Of the 100 participants, 49% received the Moderna vaccine, 43% received the Pfizer vaccine, 5% received the J&J vaccine, and 3% received the Astra Zeneca vaccine (Figure 2). The latency period between vaccination and onset of symptoms ranged from zero to 18 days. In 86% of cases, side effects occurred within the first 7 days after the vaccination. Side effects occurred in 74 patients after the first dose and in 26 patients after the second dose. The most commonly reported symptoms included tingling/vibrations/shaking feeling in 79%, numbness in 57%, heart issues in 53%, muscle weakness/muscle pain in 45%, dizziness in 44%, headache in 44%, generalized fatigue in 43%, stomach discomfort in 42%, brain fog in 39%, involuntary twitching in 36%, limb tremor in 29%, blood pressure abnormalities in 27% and tinnitus in 20% of the cases (Figure 3). In addition to these symptoms, other less commonly reported complaints have been noted, including visual disturbances, insomnia, temperature regulation issues, lymphadenopathy, menstrual irregularities, arthralgias, hypersensitivity to light and sound, skin rashes and burning sensations. Small fibre neuropathy was reported in 3 patients. Most patients had a unique set of symptoms. Of the 100 participants, 37% required hospitalization due to the severity of their complaints. However, some patients with serious side effects were not hospitalised because they were not taken seriously or because hospital capacity was reduced. Three percent of the cohort had COVID-19 prior to vaccination. Fourteen patients received the second dose despite experiencing side effects after the first dose.

DISCUSSION

The study shows that each of the licensed SARS-CoV-2 vaccines can be associated with adverse reactions. In the

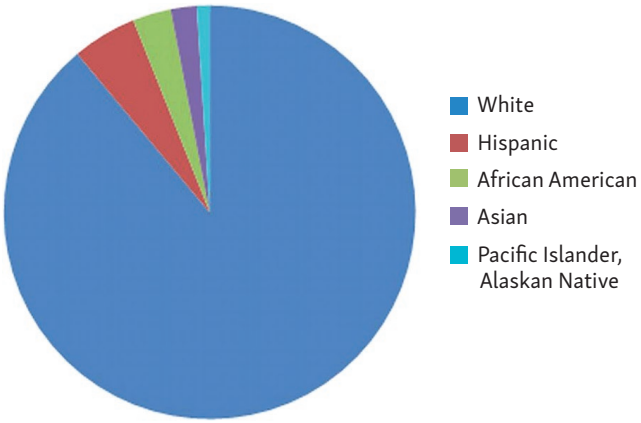

Fig. 1 Ethnic distribution of the included patients in percent.

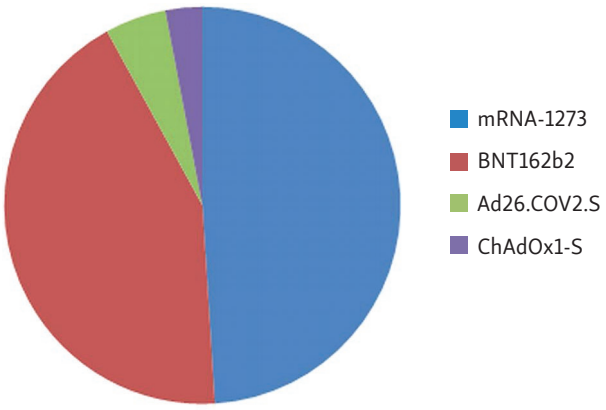

Fig. 2 Frequency of vaccine brands used in the study.

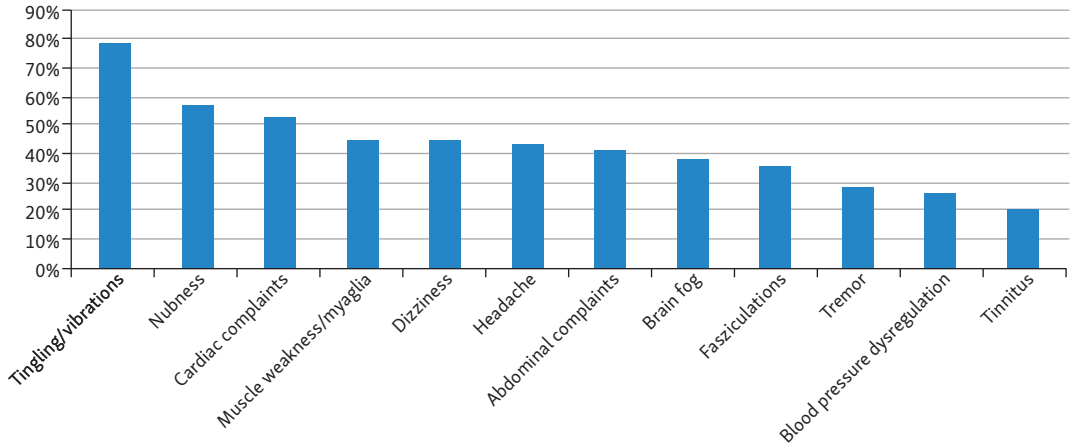

Fig. 3 Frequency of the most common side effects reported by the 100 included patients.

majority of these cases, the adverse reactions were not life-threatening, but in isolated cases serious side effects were observed, requiring hospitalization in about one third of the subjects. In view of these results, individuals should be informed about possible side effects before vaccination and, if they occur, patients should be taken seriously, and the side effects carefully reported and analyzed.

There is increasing evidence from non-industry-supported studies that SARS-CoV-2 vaccinations are not free of side effects and that all available, commercial brands can be complicated by ACVS or PACVS in previously healthy subjects, but even more so in subjects with pre-existing illnesses (3–5). In general, side effects of SARS-CoV-2 vaccination may be specific or non-specific. Specific side effects may manifest themselves in the central and peripheral nervous system (CNS/PNS), heart, intestines, blood coagulation system, lymphatic system, bone marrow, or skin. According to published data, the most common CNS complications to SARS-CoV-2 vaccination include sinus venous thrombosis, headache (6–7), acute disseminated encephalomyelitis (ADEM) (8), acute encephalitis (9), and transverse myelitis (10). PNS complications following SARS-CoV-2 vaccinations include Guillain-Barre syndrome (GBS) (11). Cardiac complications of SARS-CoV-2 vaccinations include acute myocardial damage, myocarditis or perimyocarditis (12, 13). Gastro-intestinal side effects of SARS-CoV-2 vaccination include autoimmune hepatitis, nausea, and vomiting (7). There is a report of a fatal pulmonary embolism one day after the first dose of the AstraZeneca vaccine. The lymphatic system can react with lymphadenopathy (7, 14). Bone marrow problems can manifest as hemolytic anemia (10) or immune thrombocytopenia. Dermatological manifestations following SARS-CoV-2 vaccination include bullous rash (15), erythema (7), zoster, angioedema, wheals, scaly plaques, erythematous patches, and macules and papules (16, 17). Non-specific side effects include fever, fatigue, arthralgia, swelling, chills, warmth, myalgia and local injection site reactions including induration, tenderness and itching (7, 18, 19). These previously reported nonspecific side effects are consistent with those reported in the present study. In a single-blind, randomised, controlled, phase 2/3 trial of 160 participants receiving the AstraZeneca vaccine, fatigue, headache, myalgia, and malaise were the most common side effects, but these manifestations were age-dependent (18). In a post-marketing study of 3732 participants who received the Moderna vaccine, the most common side effects reported after the first/second dose were injection site pain (93.1/92.4%), headache (44.6/70.2%), and fatigue (47.9/67.8%) (20).

The predominance of Moderna in the present study could be explained by the availability of this vaccine in the areas where an adverse reaction was reported. However, the availability of vaccines was not recorded for this study. The preponderance of women may be explained by a presumed greater interest among women in reporting their complaints. Women may also have stronger autoimmune tendencies. There is limited data on how often patients with side effects from SARS-CoV-2 vaccination require treatment, what treatment is used, and how many of those treated benefit. At present, there are currently very limited treatment options available for these adverse reactions. According to available data, a third of patients required hospitalization, which could place an additional burden on healthcare systems. There is therefore a need to develop new vaccines with fewer side effects and better tolerability.

The main limitation of the study is the small number of patients enrolled. The second limitation is that the enrolment procedures relied on selection bias. A third limitation is that no control group was included. Further limitations of the study are that no data were collected for medical clarification of the symptoms and the duration between onset and follow-up care was not documented. It remains unknown how many of the subjects reported their post-vaccination complaints to the "Vaccination Adverse Event Reporting System" (VAERS).

In conclusion, SARS-CoV-2 vaccination is not without side effects, regardless of the product used. In the case of this study, most side effects were not life-threatening, but one third of the subjects with complaints experienced serious adverse reactions that required hospitalization and intensive care treatment. Physicians should be aware that COVID-19 vaccination carries the risk of ACVS and PACVS and should take patients' post-vaccination complaints seriously. These reactions should be thoroughly documented

and reported to the appropriate health authorities, including VAERS, as well as to the vaccine manufacturers. Manufacturers of SARS-CoV-2 vaccines are urged to take side effects seriously and be cautious when promoting their current products for all age groups or for multiple booster vaccinations.

FUNDING

No funding was received.

CONFLICTS OF INTEREST

None

ETHICS APPROVAL

Only secondary data were used.

AVAILABILITY OF DATA

All data are available from the corresponding author.

AUTHOR CONTRIBUTION

JF: design, literature search, discussion, first draft, critical comments, final approval, DH: literature search, discussion, critical comments, final approval.

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