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Reports of Guillain–Barre Syndrome Following COVID-19 Vaccination in the USA: An Analysis of the VAERS Database

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Background and Purpose An association between Guillain–Barre syndrome and its variants (GBS/V) and vaccines has led to hesitancy toward vaccination. COVID-19 vaccines could theoretically provoke GBS/V via immune activation. We analyzed reports of GBS/V after COVID-19 vaccination in the vaccine adverse event reporting system (VAERS).

Methods The VAERS database is a surveillance system used to report vaccination events in the USA, and is open for consumers and physicians to access. It was queried for reports of GBS/V following COVID-19 vaccination. Reports were reviewed by four neurologists. Modified diagnostic criteria were used to classify reports into definite, possible, and not GBS/V or insufficient data. Descriptive statistics were used to describe the sample, chi-square tests and one-way ANOVAs were used to compare intergroup differences, and *t*-test were used to compare group means.

Results In 2021, 815 reports of GBS/V were filed. The completion rate for the variables in VAERS was 93.5%. The median age was 55 years (interquartile range [IQR]=5–86 years) and 50% of the subjects were male. The median time of onset was 10 days (IQR=0–298 days), 11% reported onset on the day of vaccination, and 13% reported onset after 6 weeks. Hospitalization was reported by 77%, with a median stay of 7 days (IQR=1–150 days). Lack of recovery, permanent disability, and death constituted 57%, 46%, and 2% of the reports, respectively. Based on GBS/V criteria, 47% of the cases were definite, 16% were possible, and 37% were not GBS/V or insufficient data. An alternate diagnosis was provided in 9% of cases.

Conclusions GBS/V reports following COVID-19 vaccination were common, but many occurred outside of the expected timelines for GBS/V. Only 47% of cases represented definite GBS/V.

Keywords COVID-19 vaccine; Guillain–Barre; VAERS.

INTRODUCTION

After the elimination of poliomyelitis, Guillain–Barre syndrome and its variants (GBS/V) has become the most common cause of acute flaccid paralysis worldwide.[1] GBS/V has been estimated to affect 0.4–4 persons per 100,000 annually.[2] The classic clinical presentation is ascending symmetric paralysis with areflexia, but other presentations have been recognized (GBS/V is used below to denote all presentations). Due to the archetype of an immune-mediated neuropathy, GBS/V has been associated with multiple infections as well as with some vaccines.[3] Influenza vaccination for a particularly aggressive flu strain in 1976 resulted in an increased number of GBS/V cases in the USA.[4] Associations with other vaccines and with newer flu vaccines have been less clear, although European studies have suggested that the ChAdOx1 nCoV-19 vaccine is associated with an increased GBS/V risk.[5]

COVID-19 vaccines have been developed at an unprecedented rate and are very effective at preventing severe disease and intensive care unit (ICU) admission.[6] Although the

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three COVID-19 vaccines available in the USA differ significantly from the influenza vaccine that was linked to GBS/V, there is a theoretical risk of the vaccines generating an immune response that could provoke GBS/V. A recent review of the association between COVID-19 vaccines and GBS/V suggested that GBS risk from COVID-19 vaccines was lower than that from previous vaccines for respiratory viruses; however, the search was limited to "Guillain–Barre" and encompassed only part of 2021.[7]

The vaccine adverse event reporting system (VAERS) is managed by the Centers for Disease Control and Prevention and the Food and Drug Administration, and is the national passive surveillance system in the USA for reporting vaccine-related adverse events.[8] Health-care providers, pharmaceutical companies, and consumers can file anonymous reports after experiencing postvaccination adverse events regardless of their severity or causation. Signs and symptoms are coded in VAERS using the preferred terms of the medical dictionary for regulatory activities, meaning that they are not necessarily confirmed diagnoses. Additionally, access is free to general consumers, which generates a large volume of data that is difficult to analyze. The VAERS database allows the detection of safety signals that may merit further investigation as well as hypothesis generation. In this study, we aimed to elucidate the GBS/V reports submitted to VAERS following COVID-19 vaccination.

METHODS

A structured query was performed on the VAERS database for GBS/V reports. The terms included in the search are listed in Table 1. Since GBS/V is a diverse disorder with protein nomenclature based on the clinical presentation and/or electrophysiologic findings, a wide array of terms (that were prepopulated in VAERS) was used. We also anticipated that many of the reports would have been filed by consumers and that using a wide search would allow for more comprehensive capturing of such terms. Prepopulated terms included in the search were the VAERS ID number (for case reviews), age, sex, state of residence, facility that administered the vaccination, vaccine producer, vaccine dose, symptom onset time, need for hospitalization, number of days in hospital, recovery status, disability, prior adverse reaction to vaccines, and death. Variables not prepopulated but obtained from the free-text description of the individual that filed the report included the following: need for ICU, need for mechanical ventilation, recent diarrhea, recent COVID-19 infection, recent upper respiratory infection, use of plasmapheresis (PLEX), infusion of intravenous immunoglobulin (IVIG), whether spinal magnetic resonance imaging (MRI) was performed, enhancement of spinal roots on MRI, whether a lumbar puncture (LP) was performed, elevated protein levels in the cerebrospinal fluid, whether a nerve conduction study (NCS) was performed, abnormal NCS findings consistent with GBS/V, and neurologic consultation. Categorical variables were entered into a database as 0 for absent, 1 for present, and U for unknown.

Table 1. Diagnostic terms used to search the vaccine adverse events reporting system

Guillain–Barre syndrome
Guillain–Barre syndrome variant
Miller-Fisher syndrome
Acute motor axonal neuropathy
Acute motor sensory axonal neuropathy
Acute polyneuropathy
Anti-myelin-associated glycoprotein polyneuropathy
Autoimmune neuropathy
Acute autonomic neuropathy
Axonal and demyelinating polyneuropathy
Axonal neuropathy
Demyelinating neuropathy
Immune-mediated neuropathy
Acute neuronal neuropathy
Peripheral neuropathy
Peripheral motor neuropathy
Peripheral motor/sensory neuropathy
Peripheral sensory neuropathy
Polyneuropathy
Subacute inflammatory demyelinating neuropathy
Acute toxic neuropathy

While standard GBS diagnosis criteria are often used in clinical studies, they require specific clinical information that consumers cannot provide. The VAERS data are entered in an anonymous and deidentified manner by the public and/or by health-care professionals. To circumvent this issue, we developed a classification system based on the Ashbury criteria to categorize reports from VAERS into GBS/GBS/V (Group A), possible GBS/V (Group B), and insufficient data or alternate diagnosis (Group C). Table 2 lists the modified criteria.[9] If a statement from a physician confirmed the GBS/V diagnosis, the report was coded as A; an affirmation from a physician that indicated "possible GBS" was coded as B; and reports that indicated not GBS/V, alternate diagnoses, or insufficient data were coded as C. Reports that lacked a statement from the physician were coded as A if the clinical picture was suggestive of GBS/V and if supporting laboratory data were available. The VAERS query was reviewed by four neurologists who extracted the variables and added them to a database. Cases in which the reviewers were un-

Table 2. Diagnostic criteria used for GBS/V

I. Definite GBS/V
1. Physician diagnosis of GBS/V
2. Clinical picture compatible with GBS/V (progressive weakness of one or more limbs or variant symptomatology with a course of <4 weeks) and one or more of the following
A. Spinal fluid albumin/cytologic dissociation
B. Electromyogram/NCS findings consistent with GBS/V
C. Enhanced nerve roots on MRI
D. Nerve biopsy diagnosis of acute demyelinating neuropathy or acute axonal neuropathy
II. Possible GBS/V
A. No statement that physician diagnosed GBS/V
B. Clinical picture compatible with GBS/V (as above) but lacking information on reflexes, motor/sensory examination, spinal fluid, NCS, or MRI
C. Clinical picture incomplete but abnormal spinal fluid, NCS, or MRI findings compatible with GBS/V
D. Workup described as completed (without results) and physician-instituted intravenous immunoglobulin or plasmapheresis
III. Not GBS/V or insufficient data
A. An alternate explanation available (e.g., transverse myelitis or multiple sclerosis)
B. Insufficient data
C. Clinical description not consistent with GBS/V

GBS/V, Guillain–Barre syndrome and its variants; MRI, magnetic resonance imaging; NCS, nerve conduction study.

certain about the diagnosis were independently reviewed by three neurologists to arrive at a consensus about the diagnosis.

The activities performed herein were considered exempt from the request for IRB approval due to the data being publicly available. Informed consent was not obtained, since this study used previously published deidentified information that was available to the general public under the regulation of the Centers for Disease Control and Prevention. Verification to proceed without a formal IRB review was obtained from our institution.

Statistics

Descriptive statistics were used to characterize the entire sample. Continuous variables are presented as median and interquartile range (IQR) or mean and SD values. There was no intention to infer causality from the VAERS data, but comparisons were performed among Groups A, B, and C. Continuous variables were compared among the three groups using one-way ANOVA, while categorical variables were compared using the chi-square test. Spearman's correlation coefficient was used to determine the correlation between age and GBS/V risk. GraphPad Prism (version 9.3.1; https://www.graphpad.com/scientific-software/prism/) was used for the statistical analyses.

RESULTS

In 2021, 815 reports of GBS/V following COVID vaccination were filed to VAERS. The completion rate for the prespecified data points in VAERS was 93.5% among 10,595 possible entries. Table 3 lists the general characteristics of the sample. The most common variables with missing values were vaccination site (25.7%) and number of days in hospital (19.1%). The median age of patients was 55 years (IQR=5–86 years), and 50% were male. Most vaccinations occurred in a private setting (43%), and Pfizer was the most common vaccine administered (35%). Most reports were of the first vaccination dose (41%). Fig. 1 illustrates the geographic distribution of the VAERS reports.

The median time between vaccination and symptom onset was 10 days (IQR=0–298 days). Immediate symptom onset (i.e., on the day of vaccination) was reported by 91 individuals (11%), and onset within 48 hours was reported by 162 individuals (20%). There were 635 patients (77%) hospitalized, and their median stay was 7 days (IQR=1–150 days). Lack of recovery was reported by 462 patients (57%), permanent disability was reported by 374 patients (46%), and 16 deaths were reported (2%). Tables 3 and 4 summarize the above findings.

Table 4 presents comparisons of the baseline characteristics, vaccine specifics, hospitalization needs/course, and recovery status among Groups A (n=380), B (n=129), and C (n=306). Pfizer, Janssen, and Moderna vaccinations were the most common in Groups A, B, and C, respectively. Patients in Group A were significantly more likely to require hospitalization, ICU admission, mechanical ventilation, or a prolonged length of stay. There was no difference in the recovery rates reported among the three groups. Permanent disability and not being disabled were most common in Groups C and B, respectively, while death was significantly more com-

Table 3. Characteristics of individuals who filed reports of GBS/V to the VAERS in 2021

Variable	Number	Percentage
Sex		
Female	405	49.7
Male	408	50.1
Unknown	2	0.2
Facility		
Military	10	1.2
Nursing home	7	0.9
Pharmacy	140	17
Public	69	8.5
Private	353	43.3
School	11	1.3
Work	15	1.8
Unknown	210	25.8
Vaccine		
Janssen	170	20.9
Moderna	275	33.7
Pfizer	365	34.8
Unknown	5	0.6
Vaccine dose		
First	336	41.2
Second	282	34.6
Third	52	6.4
Unknown	145	17.8
Time to symptom onset		
Known interval	798	97
Unknown interval	17	3
Median (IQR) interval, days	10 (0–298)	NA
Hospitalization		
Reported hospitalization	635	77.91
Unknown hospital stay	156	24.56
Median (IQR) hospital stay, days	7 (1–150)	NA
ICU admission	55	6.74
Mechanical ventilation	36	4.41
Recovery		
Recovered	229	28.09
Not recovered	462	56.68
Unknown recovery	124	15.21
Disability		
Permanent disability	374	45.88
No permanent disability	436	53.49
Unknown disability	124	15.21
Death		
Death reported	16	0.73

Unknown, not applicable to ICU admission/mechanical ventilation (optional VAERS entries).
GBS/V, Guillain–Barre syndrome and its variants; ICU, intensive care unit; IQR, interquartile range; VAERS, vaccine adverse event reporting system.

Fig. 1. Geographic distribution of reports of GBS and its variants following COVID-19 vaccination in the USA in 2021. GBS, Guillain–Barre syndrome.

mon in Group A.

Table 4 summarizes and lists comparisons of the diagnostic interventions, treatment modalities, and clinical courses among Groups A, B, and C. The most common diagnostic intervention performed was LP (326 patients; 40%), while the most common treatment was IVIG (230 patients; 28%). A neurologic consultation was reported by 203 patients (25%). Patients in Group A were significantly more likely to undergo LP, spinal MRI, and NCS. These patients were also more likely to have abnormal MRI findings and to undergo a neurologic consultation. They were also significantly more likely to undergo PLEX or IVIG treatment. Meanwhile, patients in Group C were significantly more likely to develop symptoms on the day of vaccination. However, the median time between onset and symptoms did not differ significantly among the three groups.

An alternate diagnosis was provided in 70 (8.6%) reports, with the most common diagnosis being of other neuropathies in 20 (28.6%), followed by focal neuropathy in 12 (17.1%), transverse myelitis in 12 (17.1%), chronic inflammatory demyelinating neuropathy in 7 (10%), vertigo in 4 (5.7%), tick paralysis in 2 (2.9%), conversion disorder in 2 (2.9%), Lyme's disease in 2 (2.9%), brain tumor in 2 (2.9%), stroke in 2 (2.9%), and other diagnosis in 7.9% of cases. The reports of 316 cases specifically indicated that the physician confirmed a GBS/V diagnosis, comprising 38.8% of all cases and 83.2% of cases in Group A. The physician diagnosed possible GBS/V in 11 cases, comprising 1.3% of all cases and 8.5% of Group B cases.

DISCUSSION

In 2021, 815 individuals used the VAERS platform to file a report of GBS/V following COVID-19 vaccination. The diagnosis was confirmed by a physician (as opposed to patient presumption) in 316 (39%) reports. In contrast, from July 1990 to June 2003, 501 reports of GBS were filed in VAERS

Table 4. Clinical characteristics, hospital stay lengths, treatments, and outcomes among patients with GBS/V reports

Variable	Group A (*n*=380)	Group B (*n*=129)	Group C (*n*=306)	Significance
Age, years	54.34±17.87	52.11±17.69	52.77±16.88	0.3344
Sex, female	158 (41.58)	68 (52.71)	179 (58.49)	0.06
Pfizer vaccine	174 (46)	34 (26)	55 (18)	0.0001
Jansen vaccine	81 (21)	46 (36)	105 (34)	0.0001
Moderna vaccine	124 (33)	47 (36)	144 (47)	0.0005
Unknown vaccine	1 (0.2)	2 (1.6)	2 (0.7)	>0.05
First vaccine dose	161 (42)	60 (47)	115 (38)	0.1855
Second vaccine dose	120 (32)	42 (33)	120 (39)	0.0977
Third vaccine dose	29 (8)	6 (5)	17 (6)	0.3697
Unknown dose number	70 (18)	21 (16)	54 (18)	0.8568
Onset to symptoms, days	22.56±31.92	17.43±24.04	25.12±50.18	0.1782
Hospitalization	350 (92)	108 (84)	177 (58)	<0.0001
Length of stay, days	11.70±17.71	7.79±12.09	5.08±10.97	<0.0001
ICU admission	45 (12)	5 (4)	5 (1.6)	<0.0001
Mechanical ventilation	31 (8.15)	3 (2.32)	2 (0.65)	<0.0001
Recovered	102 (26.84)	33 (25.58)	94 (30.71)	0.4186
Not recovered	222 (58.42)	71 (55.0)	169 (55.22)	0.6463
Recovery unknown	56 (14.73)	25 (19.37)	43 (14.05)	0.7423
Disabled	177 (46.57)	45 (34.88)	152 (49.83)	0.0172
Not disabled	199 (52.36)	83 (64.34)	154 (50.32)	0.0232
Disability unknown	3 (0.78)	1 (0.77)	0 (0)	NA
Death	12 (3.15)	1 (0.77)	3 (0.98)	0.0707
PLEX	40 (10.52)	5 (3.87)	3 (0.98)	<0.0001
IVIG	167 (43.95)	37 (28.68)	26 (8.49)	<0.0001
Combined therapy	11 (3)	3 (2)	0 (0)	NA
Spine MRI	139 (36.57)	34 (26.35)	63 (20.58)	<0.0001
Root enhancement	31 (8.15)	1 (0.77)	1 (0.32)	<0.0001
Lumbar puncture	217 (57.11)	59 (45.74)	50 (16.34)	<0.0001
Elevated protein	141 (37.11)	16 (12.41)	14 (4.58)	<0.0001
Abnormal NCS findings	65 (17.11)	15 (11.63)	11 (3.61)	<0.0001
Neurologic consultation	138 (36.32)	21 (16.23)	44 (14.38)	<0.0001

Data are *n* (%) or mean±SD values.
GBS/V, Guillain–Barre syndrome and its variants; ICU, intensive care unit; IVIG, intravenous immunoglobulin; MRI, magnetic resonance imaging; NCS, nerve conduction study; PLEX, plasmapheresis.

following flu vaccinations.[4] The seemingly disproportionate number of reports observed in our study may have been related to the ease of access to online reporting available in 2021, since such technology was not available during the 1990s. It is also conceivable that since COVID-19 vaccines were recently developed, consumers may be more vigilant about possible adverse events and more prone to filing a report. An increase in reported adverse events has previously occurred after the implementation of a new vaccine.[9]

Since VAERS is a passive surveillance system, it is subject to underreporting, reporting bias, and "stimulated reporting," among other shortcomings.[9] The widespread media attention to and increased public awareness of COVID-19 vaccines may also explain the seemingly large number of reports observed in our study. The completeness and quality of data reported to VAERS varies, and while some reports offered extreme detail that allowed a clear GBS/V diagnosis, others lacked key clinical elements to do so. Our search query encompassed reports from January 1 to December 31, 2021, and it is conceivable that further reports related to vaccination in 2021 could be filed in 2022.

In our study, we used a wide variety of terms while querying VAERS for GBS/V reports, and we did not limit our search to "Guillain–Barre syndrome." While such an approach may have increased the capture of non-GBS/V cases, it also allowed us to capture other related diseases (e.g., Miller-Fisher syndrome, acute inflammatory demyelinating neuropathy, and acute motor axonal neuropathy) that would have

been missed if narrower search terms were used. Identified neuropathies that did not qualify as GBS/V were excluded. Our approach also allowed us to infer the GBS/V diagnosis in cases that did not use a specific term but where the associated clinical/paraclinical findings supported it. Classifying the reports into definite, possible, and undetermined/not diagnosed categories may have helped to alleviate some of the limitations of VAERS. Of course, the data acquired from the VAERS analysis did not allow us to determine a causal relationship between COVID-19 vaccination and GBS/V, and is must be acknowledged that VAERS reports adverse events that are not necessarily confirmed cases. The data were also entered both by patients and by health-care professionals, and the accuracy and completeness of the information may have varied depending on who entered it. Some information entered by nonmedical individuals that facilitated the diagnosis was copy and pasted from their medical records.

We classified the VAERS reports of GBS/V into three categories based on disease probability using modified Asbury criteria (Table 2). The rationale for this classification was that since we anticipated that some reports would not contain specific terms that would have allowed us to diagnose GBS/V, implementing the criteria could have allowed the investigators to indirectly determine the diagnosis. For example, if the described symptom was "neuropathy or tingling" and the LP, NCS, or MRI findings were suggestive of GBS/V, that report was classified as GBS/V. Relying only on the Preferred Terms of the Medical Dictionary for Regulatory Activities used in VAERS would have resulted in capturing fewer reports of GBS/V. Reports submitted by consumers may lack information often used by physicians to diagnose GBS/V (e.g., reflexes, sensory examination, and time to symptom plateau), which would restrict the application of standard clinical criteria.

The reports of GBS/V to VAERS in 2021 had some striking differences relative to typical GBS/V cohorts. In most cases of GBS/V that follow immune stimulation, there is a 1- or 2-week latency, and a time interval of 3−6 days is typical following diarrhea.[1,10] In postinfluenza vaccination studies, the median time interval from vaccination to symptom onset was 13 days.[4] Similarly, in studies that analyzed the relationship between vaccines and GBS/V, events that occurred after 6 weeks were typically deemed to not be vaccine-related.[3] Almost one-third of the cases in our study reported symptom onset outside of the typically expected range for infection- or vaccine-related events. It is conceivable that a separate trigger provoked the adverse event in such cases, with COVID-19 vaccination merely being coincidental. It is also possible that minor symptoms expected at 1 day after vaccination (e.g., tingling or pain) were reported as "neuropathy" by consumers. Likewise, the number of patients who required mechanical ventilation (30%) was smaller than that expected in GBS/V.[1] Such a finding could represent underreporting of respiratory failure, since such patients tend to be sicker and less able to file a report; patients with a less-severe condition may be more able to report to VAERS. Mortality in GBS/V is typically 5%,[1] while it was 2% in our study. A higher incidence among males described in the literature was also not seen in our sample.[1]

During 2021, 815 reports of GBS/V following COVID-19 vaccination were filed to VAERS. A significant proportion of reports described the onset of symptoms occurring outside the expected time period for an event provoked by an immune trigger. Increased awareness among consumers and health-care professionals may explain the larger number of reports. Reports of GBS/V on the day of vaccination (comprising 11% of reports) were obviously not related to the vaccine. Psychogenic illness after vaccinations have been reported in many countries and may have contributed to some of the present VAERS reports.[11] For obvious reasons, historical comparisons that are available for other vaccines are not available for COVID-19 vaccines.

Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

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Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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