COVID NEWS

Guillain-Barré Syndrome Linked to COVID-19 Vaccine: CDC Study



A nurse fills a syringe with Johnson & Johnson's in Pasadena, Calif., on Aug. 19, 2021. (Robyn Beck/AFP via Getty Images)

By 2/3/2023 Updated: 2/3/2023

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A disruptive syndrome may be caused by one of the COVID-19 vaccines available in the United States, U.S. officials said in a new study.

Seventy-three cases of Guillain-Barré Syndrome, which causes the immune system to attack parts of the nervous system, were

confirmed in adults within 42 days of vaccination with Johnson & Johnson's shot, the U.S. Centers for Disease Control and Prevention (CDC) reported in the Feb. 1 paper.

Only 31 cases were expected, based on the typical annual rate of the syndrome.

Approximately 3,000 to 6,000 cases of the syndrome are diagnosed in the United States in a typical year.

Several non-COVID vaccines have been linked to Guillain-Barré Syndrome, including the swine flu vaccine.

Increased reports after the Johnson & Johnson vaccination were reported in 2021, within months of the authorization of the shot, prompting regulators to <u>add information</u> about the observed increased risk to fact sheets given to vaccine recipients and providers.

For the new paper, researchers started with reports lodged with the Vaccine Adverse Event Reporting System (VAERS), which the CDC co-manages, and worked to verify whether each report was supported by medical records and other data.

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They dug into reports of Guillain-Barré Syndrome (GBS) from Dec. 14, 2020, through Jan. 28, 2022, following vaccination with the vaccines from Johnson & Johnson, Pfizer, and Moderna. The latter two utilize messenger RNA (mRNA) technology.

Overall, researchers verified 295 cases. Numerically, most were after the mRNA vaccines. But during the time period studied, many more doses of the Moderna and Pfizer vaccines were administered.

The researchers identified a higher-than-expected number of cases after the Johnson & Johnson vaccination and a lower-than-expected number of cases for the Moderna or Pfizer vaccines.

They said that the findings "suggest that Ad26.COV2.S vaccination was associated with GBS and that GBS after BNT162b2 and mRNA-1273 may represent background incidence." Ad26.COV2.S is the trade name of Johnson & Johnson's vaccine. BNT162b2 is the trade name of Pfizer's vaccine; mRNA-1273 is the trade name of Moderna's vaccine.

None of the companies responded to requests for comment.

Limitations of the study included a lack of dose-specific analyses.

Funding sources were not listed.

The paper could not prove causation but researchers noted the results added to a growing body of research of GBS cases after vaccination with the Johnson & Johnson or AstraZeneca COVID-19 vaccines. Both are built on an adenovirus vector. AstraZeneca's vaccine has never been authorized in the United States.

U.S. officials already recommend people not get Johnson & Johnson's vaccine due to a link to thrombosis with thrombocytopenia syndrome, or low platelet levels combined with blood clotting. It is still authorized, though, for administration in the United States.

Approximately 18.9 million doses have been administered as of Feb. 2.

Deaths

Ten of the people who experienced GBS after COVID-19 vaccination died. Four of the deaths were following Pfizer vaccination, four of the deaths were following Moderna vaccination, and two were following Johnson & Johnson vaccination.

Analysis of death certificates and other records showed that GBS was listed as the cause of death for seven of the people, "however, there was no epidemiologic evidence to suggest an association between either mRNA vaccine and GBS," the CDC researchers said.

In one of the deaths after Johnson & Johnson's shot, the deceased began experiencing symptoms of the syndrome 70 days after vaccination. That's "outside an epidemiologically accepted risk interval to assume an association between vaccination and GBS," the researchers said.

The other person who died had symptoms appear five days after vaccination.

"Based on the available evidence, it is biologically plausible that Ad26.COV2.S vaccination may have been associated with the death, although definitively establishing such an association is difficult with the available information, and conclusions about causality cannot be made in this observational study," the researchers said.

Another Recent Paper

Researchers in Italy, in a paper released as a preprint on Jan. 19, identified an increased risk of GBS after both the first and second dose of Moderna's vaccine, as well as after the first dose of the AstraZeneca vaccine.

They did not detect an increased risk following Johnson & Johnson vaccination or Pfizer vaccination, even after analyzing by subgroups such as males and females.

Overall, researchers found 287 cases of GBS after COVID-19 vaccination, including 17 after Johnson & Johnson vaccination. Like the U.S. study, the risk was influenced by the number of doses administered in Italy in the time period that was studied, or Dec. 27, 2020, to Sept. 30, 2021.

The Italian researchers drew from regional healthcare databases and employed a <u>self-controlled case series</u> design, which has been <u>used elsewhere</u> to monitor vaccine safety.

Limitations of the study, which was funded by the Italian drug regulator AIFA, included not reviewing clinical records to verify

reported cases.

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