

No elevated risk for stroke seen after COVID-19 bivalent vaccine receipt

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For Medicare beneficiaries aged 65 years and older, there is no evidence of elevated stroke risk immediately after vaccination with either brand of the COVID-19 bivalent vaccine, according to a study published in the March 19 issue of the *Journal of the American Medical Association*.

Yun Lu, Ph.D., from the U.S. Food and Drug Administration in Silver



Spring, Maryland, and colleagues examined <u>stroke risk</u> after administration of either brand of the COVID-19 bivalent vaccine, COVID-19 bivalent vaccine plus a high-dose or adjuvanted influenza vaccine on the same day (concomitant administration), and influenza vaccine.

The researchers observed no significant associations between either brand of the COVID-19 bivalent vaccine and stroke outcomes during the one- to 21-day or 22- to 42-day risk window versus the 43- to 90-day control window among the 11,001 beneficiaries who experienced stroke after receiving either brand of the COVID-19 bivalent vaccine.

There was a statistically significant association noted between vaccination and nonhemorrhagic stroke during the 22- to 42-day risk window for the BNT162b2 COVID-19 bivalent vaccine and between vaccination and transient ischemic attack during the one- to 21-day risk window for the mRNA-1273.222 COVID-19 bivalent vaccine among the 4,596 beneficiaries who experienced stroke after concomitant administration. A significant association was seen between vaccination and nonhemorrhagic stroke during the 22- to 42-day risk window among the 21,345 beneficiaries who experienced stroke after influenza vaccination.

"The study by Lu et al illustrates the value of a timely, well-designed analysis and has provided reassurance about the COVID-19 boosters," Kathryn M. Edwards, M.D., and Marie R. Griffin, M.D., M.P.H., from Vanderbilt University in Nashville, Tennessee, write in an accompanying editorial.

More information: Yun Lu et al, Stroke Risk After COVID-19 Bivalent Vaccination Among US Older Adults, *JAMA* (2024). DOI: 10.1001/jama.2024.1059



Kathryn M. Edwards et al, Postmarketing Vaccine Safety Assessments, *JAMA* (2024). DOI: 10.1001/jama.2023.26630

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