Stroke Among SARS-CoV-2 Vaccine Recipients in Mexico
A Nationwide Descriptive Study

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Study Question
What is the incidence of acute stroke after immunization against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)?

What Is Known and What This Paper Adds
Information on stroke as an adverse event following immunization (AEFI) against SARS-CoV-2 remains scarce. In this nationwide study, we found that between December 24, 2020, and August 31, 2021, the incidence of stroke among recipients of 6 different anti–SARS-CoV-2 vaccines in Mexico was exceedingly rare and that most people who had a stroke had preexisting stroke risk factors.

Methods
This observational study analyzes stroke incidence as an AEFI per 1 million doses among adults (≥18 years of age). According to the World Health Organization, AEFIs were defined as clinical events occurring within 30 days after immunization and categorized as either nonserious or serious, depending on severity, treatment, and hospital admission requirements. Patients suspected of having neurologic AEFIs occurring within 30 days after receiving at least 1 dose of any approved vaccine against SARS-CoV-2 were identified through a passive epidemiologic surveillance system in which local health providers report potential AEFIs to the Mexican General Board of Epidemiology. An ad hoc committee appointed by the Mexican Ministry of Health reviewed every potentially serious neurologic AEFI, aiming to establish causality of each event. Here, we report cases of acute ischemic stroke (AIS), intracerebral hemorrhage (ICH), subarachnoid hemorrhage (SAH), or cerebral venous thrombosis (CVT) reported as neurologic AEFIs among recipients of SARS-CoV-2 vaccines.

Results and Study Limitations
Between December 24, 2020, and August 31, 2021, a total of 79,399,446 doses of 6 different anti–SARS-CoV-2 vaccines (BNT162b2, ChAdOx1 nCov-19, Gam-COVID-Vac, CoronaVac, Ad5-nCoV, and Ad26.COV2-S) were administered in Mexico. We identified 56 patients who had a stroke as an AEFI (31 female [55.5%]) for an overall incidence of 0.71 cases per 1,000,000 administered doses (95% CI 0.54–0.92). Among the 56 people with a stroke, the median age was 65 years (interquartile range [IQR] 55–76 years); median time from vaccination to stroke (of any subtype) was 2 days (IQR 1–5 days). In 27 (48.2%) people, the event was diagnosed within the first 24 hours after immunization. The most frequent subtype was AIS in 43 people (75%; 0.54 per 1,000,000 doses, 95% CI 0.40–0.73), followed by ICH in 9 (16.1%; 0.11 per 1,000,000 doses, 95% CI 0.06–0.22) and SAH and CVT, each with 2 cases (3.6%; 0.03 per 1,000,000 doses, 95% CI 0.01–0.09). Overall, the most common risk factors were hypertension in 33 (58.9%) patients and diabetes in 22 (39.3%); median hospital length of stay was 6 days (IQR 4–13). At discharge, functional outcome was good in 41.1% of patients (modified Rankin Scale score 0–2), and the in-hospital mortality rate was 21.4%. The limitations of the present study include its descriptive nature, the passive nature of the Mexican epidemiologic surveillance system, and the fact that, because reports rely on local health care providers, some stroke subtypes may be underdiagnosed, particularly cases presenting with mild or nondisabling symptoms or sequelae.

Table Observed Stroke Incidence According to Vaccine

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Total doses, n</th>
<th>Cases, n</th>
<th>Incidence (95% CI) *</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNT162b2</td>
<td>24,416,970</td>
<td>17</td>
<td>0.70 (0.43–1.12)</td>
</tr>
<tr>
<td>ChAdOx1 nCov-19</td>
<td>29,157,558</td>
<td>23</td>
<td>0.79 (0.53–1.18)</td>
</tr>
<tr>
<td>CoronaVac</td>
<td>13,006,520</td>
<td>9</td>
<td>0.65 (0.34–1.23)</td>
</tr>
<tr>
<td>Gam-COVID-Vac</td>
<td>4,450,465</td>
<td>1</td>
<td>0.22 (0.04–1.27)</td>
</tr>
<tr>
<td>Ad5-nCoV</td>
<td>5,122,301</td>
<td>6</td>
<td>1.17 (0.54–2.56)</td>
</tr>
<tr>
<td>Ad26.COV2-S</td>
<td>1,345,632</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>All vaccines</td>
<td>79,399,446</td>
<td>56</td>
<td>0.71 (0.54–0.93)</td>
</tr>
</tbody>
</table>

Abbreviation: NA = not applicable.
* Incidence per 1,000,000 doses administered.

Registration, Study Funding, and Competing Interests
The study approved by the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (NER-3903-21-23-1) Ethics and Research Committees. This study did not receive targeted funding. The authors report no competing interests. Go to Neurology.org/N for full disclosures.
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