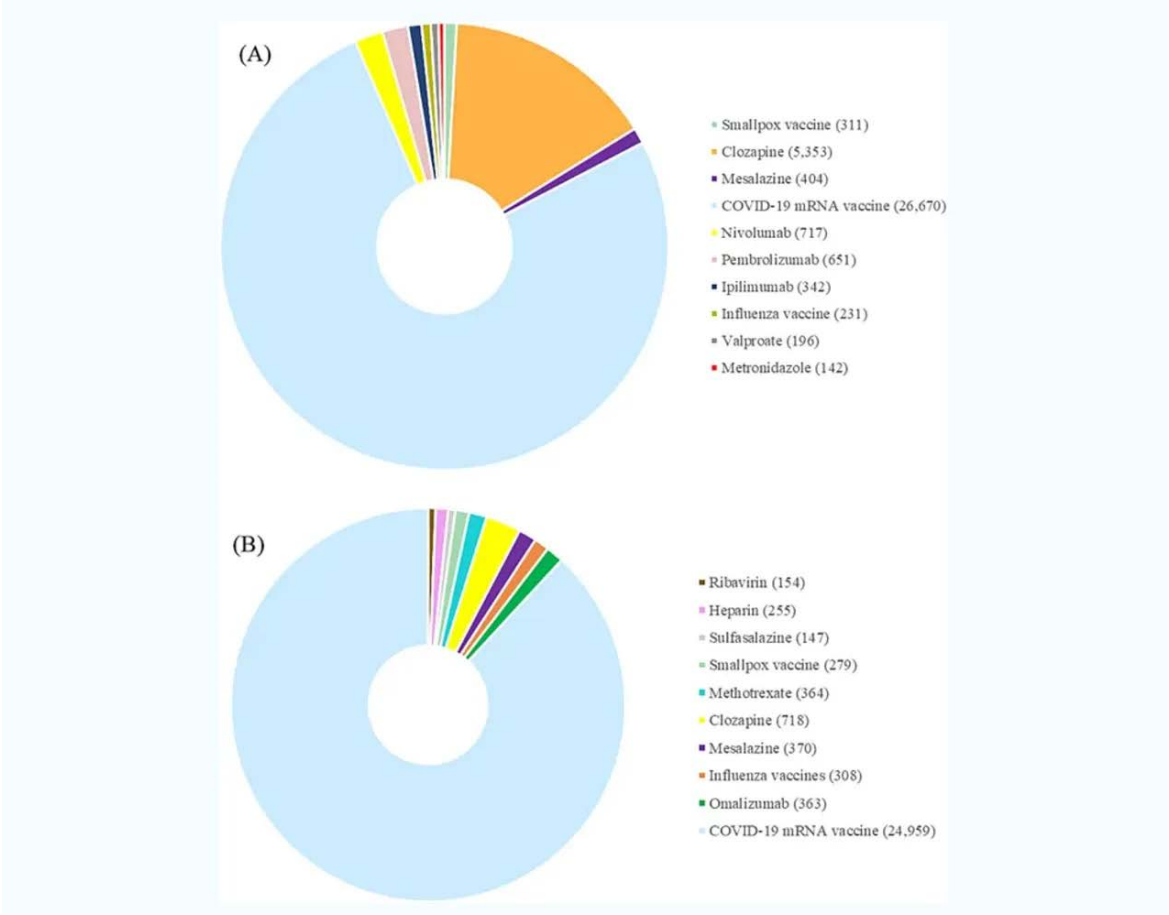
Global Data Bombshell: COVID-19 mRNA Vaccines Top List of Drugs Most Often Reported with Heart Inflammation

From: Trial Site News

ROBERT W MALONE MD, MS
AUG 12, 2025



Global Data Bombshell: COVID-19 mRNA Vaccines Top List of Drugs Most Often Reported with Heart Inflammation

From: Trial Site News

two potentially life-threatening heart inflammations — myocarditis and pericarditis — across more than five decades of safety reports. The hypothesis: that certain widely used drugs, including vaccines, are disproportionately reported alongside these conditions. The results are striking, even unsettling to say the least: COVID-19 mRNA vaccines accounted for the vast majority of reported cases in both categories, raising complex, and frankly, troubling questions for clinicians, regulators, and the public.

Study Design & Method

The team mined the world's largest repository of adverse drug reaction reports — over 35 million records from 140+ countries - covering 1968–2024. They excluded drugs already used to treat heart inflammation to avoid confounding, then ranked the top 10 most frequently reported drugs for each condition. Statistical "signal detection" was performed using reporting odds ratios (ROR) and Bayesian information components (IC), tools that flag disproportionately high associations.

Dong Keon Yon, Co-Corresponding Author

Source: Kyung Hee University

Findings

The numbers are staggering:

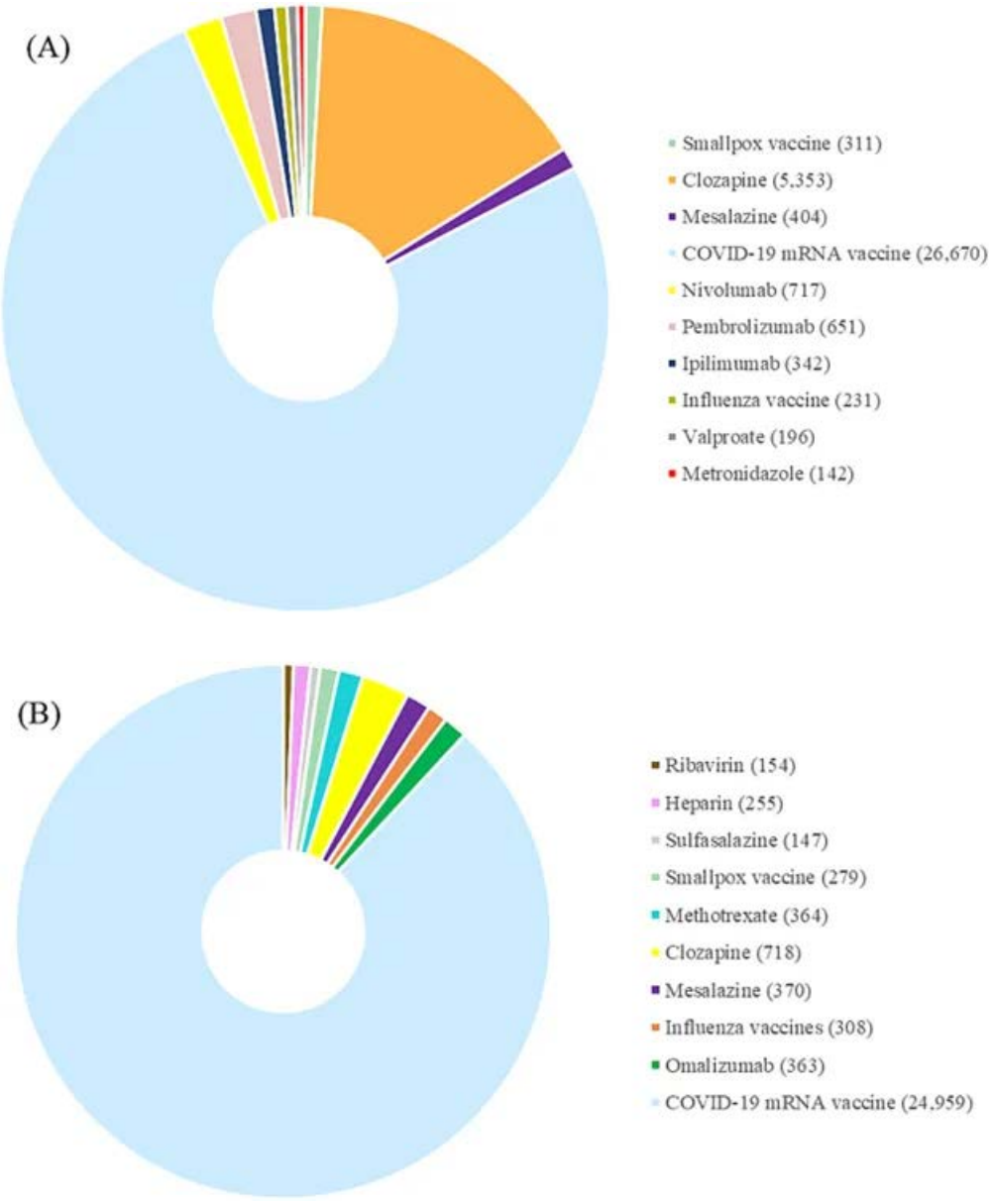
- **Myocarditis: 35,017 total reports; 76.16% (26,670 cases) linked to COVID-19 mRNA vaccines, followed by clozapine (15.29%).**
- **Pericarditis: 24,959 reports; 88.15% (22,001 cases) linked to COVID-19 mRNA vaccines, with no other drug exceeding 10%.**

Other consistent signals included smallpox and influenza vaccines, clozapine, and mesalazine. Immune checkpoint inhibitors (nivolumab, pembrolizumab, ipilimumab) showed disproportionately high fatality rates in myocarditis cases (~20%). Alarmingly, the highest statistical signals were in youth aged 0–17 for both

conditions.

A surge in case reports appeared in 2021 — coinciding with mass COVID-19 vaccination campaigns and the pandemic's acute phase. While the study cannot prove causality, the sheer proportion of vaccine-associated reports demands further scrutiny.

Proportion distribution of reports of myocarditis (A) and pericarditis (B) adverse events with different drugs.



Source: *Scientific Reports*

TrialSite Perspective

One of the most unsettling revelations in the study is the disproportionately high statistical signal for myocarditis and pericarditis in the 0–17 age group — a population in which COVID-19 has been overwhelmingly mild to moderate for roughly 95%+ of cases, and even more so in the post-Omicron era.

True severe outcomes such as MIS-C were rare and largely concentrated during the Delta variant surge. When weighed against the generally lower infection risk profile of youth — bolstered by widespread pre-existing exposure and residual natural immunity — the emergence of elevated heart inflammation signals in this cohort may profoundly reshape the risk-benefit equation even more than we already know.

In this context, U.S. Health and Human Services Secretary Robert F. Kennedy Jr.'s recent decision to remove the formal recommendation for COVID-19 vaccination in young children gains new relevance. The data underscore the ethical imperative for targeted, age-stratified public health policy — especially when a medical intervention shows heightened adverse event reporting in a group with minimal baseline risk from the disease itself.

Limitations

The dataset depends on spontaneous reporting, vulnerable to underreporting, overreporting, and diagnostic uncertainty. Media attention heightened clinical vigilance, and massive vaccine rollout campaigns may have amplified report volumes — a phenomenon known as stimulated reporting. No incidence rates can be derived, and causality cannot be confirmed by these associations alone.

Funding & Disclosure

Funded by multiple South Korean government research grants. Authors declare no competing interests.

Conclusion & Implications

This global analysis signals a clear need for targeted cardiac safety monitoring, especially in younger populations and males, where myocarditis risk appears elevated. Clinicians should be alert to symptoms of chest pain, shortness of breath, or palpitations in the days after certain vaccinations or high-risk drug exposures. Policymakers face a delicate balancing act: these findings do not erase the substantial benefits of vaccines but underscore the ethical imperative for transparency, patient education, and tailored risk mitigation strategies.

In the words of one cardiologist reviewing the data, “This is not an anti-vaccine study — it’s a call to refine how, when, and to whom certain medicines are given.”

TrialSite Evidence Strength Indicator™

TrialSite Evidence Strength Indicator™		
Factor	Score (0–10)	Rationale
Study Design & Scale	9	Largest-ever pharmacovigilance dataset; multi-decade scope.
Statistical Rigor	8	Robust disproportionality methods; age/sex stratification.
Data Limitations	5	Spontaneous reports prone to bias; no causality or incidence rates.
Funding & COI Transparency	10	Public funding; no conflicts declared.
Real-World Applicability	7	Signals relevant to clinical vigilance but require cautious interpretation.
Overall Score: 78%		Large-scale, statistically robust, but limited by reporting bias and no causality.

Citation: Cho, J., Jo, H., Park, J., et al. “Top 10 drugs most frequently associated with adverse events of myocarditis and pericarditis.” *Scientific Reports*. Published August 7, 2025. doi:10.1038/s41598-025-13234-6