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Original article

COVID-19 Vaccines: A Risk Factor for Cerebral Thrombotic Syndromes

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Abstract

Introduction: This population-based retrospective cohort study assesses rates of adverse events (AEs) involving cerebral thromboembolism (CTE) after COVID-19 vaccines. ***Methods:*** Data were collected from the U.S. Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) database from January 1, 1990 to December 31, 2023. CTE AEs after COVID-19 vaccines were compared to those after influenza vaccines and after all other vaccines using proportional reporting ratio (PRR) analysis by time. ***Results:*** There are 5137 cerebral thromboembolism AEs reported in the 3 years (36 months) after COVID-19 vaccines compared to 52 AEs for the influenza vaccines over the past 34 years (408 months) and 282 AEs for all other vaccines (excluding COVID-19) over the past 34 years (408 months). The PRR's are significant when comparing AEs by time from COVID-19 vaccines to that of the influenza vaccines ($p < 0.0001$) or to that of all other vaccines ($p < 0.0001$). The CTE AEs PRR by time (95% confidence intervals) for the COVID-19 vaccine AEs vs influenza AEs is 1120 (95% confidence interval (723-1730), $p < 0.0001$) and for COVID-19 vaccines vs all others is 207 (95% confidence interval (144-296), $p < 0.0001$). Cerebral venous thromboembolism AEs are female predominant with a female/male odds ratio of 1.63 (95% confidence interval (1.52-1.74), $p < 0.0001$). Conversely, cerebral arterial thromboembolism has a nonsignificant male preponderance. Cerebral venous thromboembolism is far more common than cerebral arterial thromboembolism over 36 months with an odds ratio (OR) of 14.8 (95% confidence interval 14.0-15.5, $p < 0.0001$). Atrial fibrillation, the most common identifiable cause of cerebral arterial thromboembolism, occurs far more commonly after the COVID-19 as compared to all other vaccines with a PRR of 123 (95% CI 88.3-172, $p < 0.0001$). ***Conclusions:*** There is an alarming breach in the safety signal threshold concerning cerebral thrombosis AEs after COVID-19 vaccines compared to that of the influenza vaccines and even when compared to that of all other vaccines. An immediate global moratorium on the use of COVID-19 vaccines is necessary with an absolute contraindication in women of reproductive age.

Keywords: ***thrombosis, cerebral thromboembolism, Sars-CoV-2, COVID-19 vaccine, spike protein.***

Plain language title and summary

COVID-19 Vaccines: A Risk Factor for Stroke

This research sought to determine if there is an increased risk of stroke in patients after receiving the COVID-19 vaccine. Cerebral venous thrombosis was of particular interest because this rare variant of stroke is generally seen in younger women of child-bearing potential due to the physiological risk factors inherent to this patient population. Using the U.S. Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) Vaccine Adverse Events Reporting System (VAERS), reports of stroke were extracted from January 1, 1990 to December 31, 2023. VAERS case numbers after the COVID-19 vaccines were compared to the numbers after the influenza vaccines as well as to all vaccines in the database. There were 5137 cases of cerebral thromboembolism in 36 months after COVID-19 vaccines compared to 52 cases for the influenza vaccines over a period of 408 months and 282 cases for all other vaccines (excluding COVID-19) in 408 months. The alarming number of reports of stroke in VAERS after the COVID-19 vaccines over a much shorter period of time demonstrate an unacceptable risk for this serious complication.

Introduction

In 1856 Rudolph Virchow, a German pathologist, recognized three factors that led to thromboembolism: vascular stasis, hypercoagulability, and vascular trauma. This has withstood the test of time and is commonly referred to as Virchow's Triad [1]. The overall prevalence of cerebral venous thrombosis (CVT) in adults is estimated to be about one per 100,000 people per year although sex-specific risk factors include women, contraceptive use, pregnancy, puerperium, and hormone replacement therapy. A gradual increase

in the incidence has been observed over time in women. The incidence of CVT in women ages 31-50 years is around three per 100,000 people per year [2].

Many clinicians have observed a substantial increase in CTE since the rollout of the COVID-19 vaccines. The legally mandated Pfizer's post-marketing analysis was conducted from the start of the public rollout on about December 10, 2020 to February 28, 2021. This Pfizer document noted their COVID-19 vaccine to be the most lethal and injurious drug ever rolled out to the public with 42,086 casualties including 1,223 deaths in just the first 10 weeks of rollout [3]. Pfizer and the FDA attempted to conceal the post-market analyses of adverse events for 55-75 years [4,5]. The government concurrently invested unprecedented amounts of US tax dollars to promote the safety, efficacy, and necessity of the COVID-19 vaccines even in the most vulnerable population: pregnant women, preborns, and newborns. Many researchers across the globe estimate that the vaccine has killed far more people than it has saved [6-10].

Sir Karl Popper believed that scientific knowledge is provisional and refutes the "positivist account of the scientific method" and should be replaced by the "induction with falsification principle". By using observations, as Popper stated, science progresses by falsification and refutation of reigning scientific narratives [11]. By Karl Popper's reasoning, the reigning narrative that the COVID-19 vaccines are safe, effective, and necessary originally taken on faith by the medical community has decidedly been falsified and refuted. There are now 3,580 studies published in peer-reviewed medical journals documenting injuries, disabilities, and deaths after COVID-19 vaccines [12]. Additionally, Janssen and AstraZeneca adenoviral vaccines have been removed from markets globally [13,14].

The purpose of this report is to query the US Centers for Disease Control (CDC) and US Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) for the safety signals of venous/arterial thromboembolism after vaccination.

Methods

The US Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) were used to extract the data with the MedAlerts.org platform. VAERS uses the MedDRA (medical dictionary for regulatory activities), a clinically validated international medical terminology used for regulatory and biopharmaceutical purposes [15]. In VAERS we used the MedDRA "lowest level terms" (LLT's) for this investigation. Noteworthy is that MedDRA LLT's are in British rather than American spellings which results in some challenges for queries; for example, "ischaemic" in this particular report. The following 12 "symptoms" were extracted from VAERS using the MedDRA LLT's referred to hereafter as cerebral thromboembolism CTE adverse events (AEs).

1) 'cavernous sinus thrombosis', 2) 'cerebral artery thrombosis', 3) 'cerebral infarction', 4) 'cerebral thrombosis', 5) 'cerebral venous sinus thrombosis', 6) 'cerebral venous thrombosis', 7) 'embolic cerebral infarction', 8) 'ischaemic cerebral infarction', 9) 'sigmoid sinus thrombosis', 10) 'superior sagittal sinus thrombosis', 11) 'thrombotic cerebral infarction', and 12) 'transverse sinus thrombosis'.

Using the AEs above, the VAERS database was analyzed from January 1,1990 through December 31, 2023 thus yielding 3 years (36 months) of COVID-19 vaccine data and 34 years (408 months) for all other vaccines.

The pathophysiological basis for these 12 CTE AEs falls into three clinically distinct and separate categories:

1) Cerebral venous thrombosis (CVT): 'cavernous sinus thrombosis', 'cerebral venous sinus thrombosis', 'cerebral venous thrombosis', 'sigmoid sinus thrombosis', 'superior sagittal sinus thrombosis', 'transverse sinus thrombosis';
2) Cerebral thrombosis undetermined as to arterial or venous etiology (CTU): 'cerebral infarction', 'cerebral thrombosis', 'embolic cerebral infarction', 'ischaemic cerebral infarction', thrombotic cerebral infarction'
3) Cerebral arterial thrombosis (CAT): 'cerebral artery thrombosis'.

Statistical analysis for proportional reporting ratios (PRR) based on AEs per time, per dose, and per individual vaccinated was performed in a previous publication utilizing Poisson distribution and Monte Carlo Simulations. Because the findings of AEs per dose and per individual vaccinated were similar to AEs per time, these analytics were not repeated [16].

Since atrial fibrillation is the most common identifiable cause of cerebral arterial thromboembolism, [17] MedAlerts was queried on 5/4/2024 to analyze atrial fibrillation cases with the last release of VAERS reports from 4/26/2024. We compared reports for atrial fibrillation following COVID-19 vaccines from December 1, 2020 to April 26, 2024 (41 months) to all other vaccines between the dates of January 1, 1990 through April 26, 2024 (412 months).

The preferred methods of analytics were used according to the standards set forth by FDA/CDC/VAERS for what is historically considered a "safe vaccine" compared to that of the novel vaccine, thus providing a proportional reporting ratio (PRR). The COVID-19 vaccine AEs were compared to those associated after the influenza vaccines and to all vaccines. According to the CDC's standard operating procedures for the analysis of COVID-19 vaccine AEs, a PRR ≥ 2 is a safety concern [18]. Standard statistical methods were used including reporting ratios and 95% confidence intervals using the MedCalc statistical software [19].

Results

Table 1: The raw data extracted from VAERS database from January 1,1990 through December 31, 2023 including 36 months of COVID-19 vaccine data and 408 months for influenza as well as all other vaccines. Column 1 includes the 12 "symptoms" exactly as described in the VAERS lowest level terms in MedDRA.

Adverse Events (AEs) VAERS	Total AEs reported over 408 months	COVID-19 vaccine AEs over 36 months	Influenza vaccine AEs over 408 months	All other vaccines AEs over 408 months
Cavernous sinus thrombosis	24	20	3	4
Cerebral artery thrombosis	103	99	1	4
Cerebral infarction	2799	2623	35	176
Cerebral thrombosis	640	612	5	28
Cerebral venous sinus thrombosis	896	874	1	22
Cerebral venous thrombosis	372	345	1	27

Embolic cerebral infarction	60	57	1	3
Ischaemic cerebral infarction	247	238	2	9
Sigmoid sinus thrombosis	10	10	0	0
Superior sagittal sinus thrombosis	88	86	0	2
Thrombotic cerebral infarction	47	46	0	1
Transverse sinus thrombosis	133	127	3	6

Table 1 summarizes the raw data extracted from VAERS database from January 1,1990 through December 31, 2023, including 36 months of COVID-19 vaccine data and 408 months for influenza as well as all other vaccines.

Table 2: Based upon the three clinically distinct pathophysiologies, the 12 "symptoms" of interest in the VAERS lowest level MedDRA terms were separated into three distinct categories: cerebral venous thrombosis (CVT), cerebral thrombosis undetermined as to the arterial/venous source (CTU), and cerebral arterial thrombosis (CAT). The raw data from Table 1 are included in these separate categories and totaled in the last row.

Category of Thrombosis	COVID-19 vaccines over 36 months	Influenza vaccines over 408 months	All other vaccines over 408 months
Cerebral Venous Thrombosis (CVT)	1462	8	61
Cerebral Thrombosis Undetermined (CTU)	3576	43	217
Cerebral Arterial Thrombosis (CAT)	99	1	4
Total Cerebral Thromboembolism (CTE)	5137	52	282

Table 2 categorizes the raw data into three clinically distinct pathophysiologic categories of the 12 "symptoms" of interest in VAERS. These include cerebral venous thrombosis (CVT), cerebral thrombosis undetermined as to the arterial/venous source (CTU), and cerebral arterial thrombosis (CAT).

Table 3: The proportional risk ratios (PRR) of COVID-19 vaccines versus influenza vaccines (Column 2) and COVID-19 vaccines versus all other vaccines (Column 3) for each category CVT, CTU, CAT, CTE (by rows). There is a significant increase in cerebrovascular thrombosis for all categories ($p < 0.0001$).

Category of Thrombosis	COVID-19 Vaccines over 36 Months vs Influenza Vaccines over 408 Months PRR (95% Confidence Interval)	COVID-19 Vaccines over 36 Months vs Other Vaccines over 408 Months PRR (95% Confidence Interval)
Cerebral Venous Thrombosis (CVT)	2070 (955 - 4490) P < 0.0001	272 (177 - 416) P < 0.0001
Cerebral Thrombosis Undetermined (CTU)	943 (598 - 1480) P < 0.0001	187 (129 - 270) P < 0.0001)
Cerebral Arterial Thrombosis (CAT)	1120 (152 - 8280) P < 0.0001	281 (97.6 - 806) P < 0.0001
Cerebral Thrombosis Total (CTE)	1120 (723 - 1730) P < 0.0001	207 (144 - 296) P < 0.0001

Table 3 demonstrates the proportional risk ratios (95% CI, p value) of COVID-19 vaccines versus Influenza vaccines (Column 2) and COVID-19 vaccines versus all other vaccines (Column 3) for each category CVT, CTU, CAT, CTE (by rows). There is a significant increase in cerebrovascular thrombosis for all categories ($p < 0.0001$).

Table 4: The female / male odds ratios in the comparison of CTE AEs after COVID-19 vaccine by cerebral venous thrombosis (CVT), cerebral thrombosis undetermined as to venous or arterial (CTU), cerebral arterial thrombosis (CAT) and cerebral thrombosis total (CTE).

Adverse Events (AEs)	COVID-19 Vaccine AEs over 36 Months	Female/Male Odds Ratio (95% confidence interval)
Cerebral Venous Thrombosis (CVT)	Female / Male / Unknown 11 / 9 /0 545 / 318 / 11 211 / 132 / 2 5 / 4 / 1 46 / 38 / 2 77 / 48 / 2 **Totals 895 / 549 / 18**	Female / Male 1.63 (1.52 - 1.74)
Cerebral Thrombosis (undetermined as to venous or arterial) (CTU)	Female / Male / Unknown 1300 / 1297 / 26 314 / 292 / 6 22 / 35 / 0	Female / Male 0.99 (0.95 - 1.04)

	106 / 132 / 0 25 / 21 / 0 **Total 1767 / 1777 / 32**	
Cerebral Arterial Thrombosis (CAT)	**47 / 50 / 2**	Female / Male 0.94 (0.69 - 1.25)
Cerebral Thrombosis Total (CTE)	**2709 / 2376 / 52**	Female / Male 1.14 (1.10 – 1.18)

Table 4 depicts the female / male odds ratios in the comparison of CTE AEs by cerebral venous thrombosis (CVT), cerebral thrombosis undetermined as to venous or arterial (CTU), cerebral arterial thrombosis (CAT) and cerebral thrombosis total (CTE). As expected, CVT had the highest female / male ratio 1.63 (1.52 - 1.74), followed by CTE 1.14 (1.10 – 1.18), followed by CTU 0.99 (0.95 - 1.25), and lastly CAT which has a non-significant male preponderance 0.94 (0.69 - 1.25).

Table 5: CTE AEs after COVID-19 vaccines are stratified by age and sex dates from 1/1/1990 through 12/31/2023. The female / male ratio in age group 18-59 years is 1.28 (676/527) with a 95% confidence interval of 1.19 - 1.38.

Age	**Sex**		
	Female	**Male**	**Unknown**
18-29 years	134	43	3
30-39 years	136	83	1
40-49 years	202	146	0
50-59 years	204	255	1
Total	676	527	5

Table 5 compares data in the age range of greatest prevalence for CTE cases with vaccination dates from 1/1/1990 through 12/31/2023. The sex disparities in AEs after COVID-19 vaccination are stratified by age and sex. The female / male ratio in age group 18 - 59 years is 1.28 (676/527) with a 95% confidence interval of 1.19 - 1.38.

Atrial fibrillation is the most common identifiable risk factor for cerebral arterial thromboembolism which is one of the leading causes of morbidity and mortality globally [17]. MedAlerts was analyzed for atrial fibrillation cases comparing COVID-19 vaccines from December 1, 2020 through April 26, 2024 (41 months) to all other vaccines between the dates of January 1, 1990 through April 26, 2024 (412 months). There are 9,821 reports of atrial fibrillation after COVID-19 vaccines in 41 months compared to 797 cases reported in 412 months for all other vaccines combined. The Proportional Risk Ratio (PRR) for atrial fibrillation associated with COVID-19 vaccines compared to all other vaccines in the database is 123 with a 95% confidence interval 88.3-172, $p < 0.0001$.

Discussion

Cerebral venous thrombosis (CVT) is a rare disorder characterized by thrombus formation within the cerebral veins or dural sinuses. The annual incidence ranges from 1.16 to 2.02 per 100,000 and is encountered more predominantly in female patients. Additionally, CVT affects a younger patient population than what is seen in arterial strokes, with a median age of 37 years with one study citing only 8% of patients were over the age of 65 [20]. Diagnosis of this condition is challenging for clinicians due to the wide and variable clinical presentation including headache, papilledema, visual loss, focal or generalized seizures, focal neurologic deficits, confusion, altered consciousness, and coma [21,22]. Typical risk factors for the development of CVT include inherited prothrombotic conditions, brain tumors, trauma, infections, hematological diseases, medications, surgery, pregnancy, and puerperium, amongst others [23].

Cerebral embolisms are one of the most common causes of morbidity and mortality globally. The global incidence rate of embolic (ischemic) strokes varies widely between countries and regions. Rates in the United States range from 74 per 100,000 to 329 per 100,000 people with males having the preponderance of cases [24]. Unlike cerebral thrombosis, a cerebral embolism occurs when a clot travels to the brain from elsewhere in the body, usually the heart. Symptoms vary greatly depending on the location of the embolus but often results in a painless acute neurological deficit. Risk factors include history of stroke, increasing age, hypertension, smoking, hypercholesterolemia, heart disease, diabetes, and high alcohol intake [25]. The most common identifiable risk factor for a cerebral arterial thromboembolism is atrial fibrillation [17]. Of interest, there were 3,554 cases of atrial fibrillation reported after COVID-19 vaccination in the Pfizer clinical trial post-marketing documents [26].

The Sars-CoV-2 vaccines were necessarily developed rapidly without the standard 10-15 years of development and testing to establish safety [27]. The vaccines were subsequently approved under Emergency Use Authorization (EUA) in response to the novel viral pathogen, Sars-CoV-2, that rapidly spread across the globe leaving chaos, fear, and death in its wake. Early in the COVID pandemic, it became evident that there was a thrombogenic effect of the Sars-CoV-2 virus and it is now believed that the spike protein is one of the major contributors to this thrombogenic effect [28,29]. As expected, the same thromboembolic effects have been noted post-vaccination, likely a result of the spike protein component of the vaccine.

During the first wave of infection with the original Wuhan strain of the virus, hospitalized patients experienced a variety of severe thromboembolic events and, over time, natural evolution may have resulted in less virulent strains. Subsequently, the hypercoagulability concerns from serious thromboembolic events seen in 2020 have diminished. However, fibrin-amyloid aggregates affecting the smaller vessels in the circulatory system known as “microclots” are being discussed globally as one of the main mechanisms driving Long COVID and vaccine injury [30]. Microclots circulate and deposit throughout the body having potential detrimental effects on every organ system, yet no standardized diagnostic test or treatment algorithm exists.

Although the virus alone is not driving a substantial number of thromboembolic events, it is now widely understood that cumulative exposure to the spike protein, either from the virus or

vaccine, greatly increases prothrombotic coagulopathy risks in patients [31]. This is a significant factor as most of the population has either been infected with the Sars-CoV-2 virus or taken the COVID vaccine(s), while many have had both. As documented by Statista, up to 80.3% of the US population has taken at least one COVID vaccine [32].

A NIH National Library of Medicine PubMed search on various thrombotic diagnoses confirms the alarming trend that we are seeing in the general population: there was a significant increase in the case reports and scientific papers on this topic between 2020 and 2021 with a notable variable being the rollout of the COVID vaccines during this time frame. A peer-reviewed publication in 2022 documented that there were 1,366 peer-reviewed medical journal articles published in just 16 months that document injuries and deaths after COVID-19 vaccines. This manuscript published and categorized these 1,366 articles with the most common categories being myocarditis/pericarditis in 336 articles, vaccine-induced thrombotic thrombocytopenia in 209 articles, and 160 articles regarding arterial and venous thromboembolism [33]. Hisano and colleagues published findings of their recent study in which anti-phospholipid antibodies were found in the serum of the study participants post-vaccination. Persistence of these antibodies are associated with antiphospholipid syndrome, one of the potential mechanisms behind various thrombotic adverse events post-vaccination, including recurrent miscarriages [34].

There are many strengths of this study. The open-source VAERS database used for this investigation is regulated, owned, and maintained by the CDC/FDA. These entities continue promoting COVID-19 vaccines in all patients, even the most vulnerable population, pregnant women, while making fraudulent claims of safety and efficacy. Despite the bias of the CDC/FDA and their attempts to hide, conceal, and "throttle" the deaths and injuries caused by the COVID-19 vaccines, there remains an unprecedented breach of the safety signal using their own criteria [35-37].

The limitations to this study are those inherent to the CDC/FDA's VAERS database. The relative underreporting factor (URF) in VAERS is thought to be in the range of 30-100. This factor, which irrefutably and substantially reduces the danger signals, determines that the number of adverse events associated with the vaccines cannot confidently be known. The URF may be attributed to several reasons [38-40]. It has been reported that there is tremendous difficulty in VAERS processing because the CDC staff are overwhelmed with adverse effect reports [41]. Many clinicians do not possess the knowledge necessary to recognize, evaluate, report, or treat vaccine AEs. The VAERS database is well known for its difficulty in entering events, making it even more challenging for healthcare workers to submit each event with limited time in a hospital or clinic setting.

This study demonstrates a significant breach in the safety signal threshold concerning COVID-19 vaccines' association with an increased risk of cerebral venous thrombosis as compared to that of influenza vaccines as well as all other vaccines. Prior to the COVID-19 vaccine rollout, the prevalence of CVT was far less common than CAT with a reported ratio of 1:62.5 [42]. Females represent a far greater proportion of the cases of cerebral venous thrombosis which is likely associated with the greater risk of CTE in pregnancy, puerperium, contraceptive use, and hormonal replacement therapy.

Conclusion

This study demonstrates a significant breach in the safety signal threshold concerning the association of COVID-19 vaccines with an increased risk of cerebral venous thrombosis as compared to that of influenza vaccines as well as all other vaccines (excluding COVID-19). The CTE AEs when analyzed using PRR by time (95% confidence interval) for the COVID-19 vaccine AEs vs influenza AEs is 1120 (95% confidence interval (723-1730), $p < 0.0001$) and for COVID-19 vaccines vs all others is 207 (95% confidence interval 144-296, $p < 0.0001$). Females represent a far greater proportion of the cases of cerebral venous thrombosis with a female / male odds ratio of 1.63 (95% confidence interval 1.52-1.74, $p < 0.0001$), likely associated with the greater risk of CTE in pregnancy, puerperium, contraceptive use, and hormonal replacement therapy. An immediate global moratorium on the use of COVID-19 vaccines is necessary to mitigate further risk with an absolute contraindication in women of reproductive age.

Declarations

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Author Contributions

CR: data curation, investigation, methodology, project administration, supervision, validation, writing - original draft, writing - review & editing.
JT: conceptualization, data curation, formal analysis, investigation, methodology, project administration, supervision, writing - original draft, writing - review & editing
KC: data curation, investigation, validation, writing - review & editing
PM: formal analysis, investigation, methodology, supervision, validation, writing - review & editing

Statements and declaration

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Consent to participate

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Consent for publication

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Data availability

Raw data collected for and outlined in this paper may be obtained by searching the VAERS database at https://medalerts.org/vaersdb/index.php.

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