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Comparative Risks Cardiovascular Adverse Events of COVID-19 and other Vaccines

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KEYWORDS

COVID-19 vaccines, Myocarditis, Pericarditis, Cardiomyopathy, Cardiac Arrhythmia, Myocardial Infarction.

ABSTRACT

Introduction: This population-based study reviewed rates of adverse events (AE's) involving cardiac disease after COVID-19 vaccines.

Methods: Data were reviewed from the US Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) from January 1, 1990 through

May 5, 2023. The proportional risk ratio (PRR) compares AEs after COVID-19 vaccines with those reported after Influenza vaccines and all other vaccines except COVID-19.

Results: Crude cumulative AE data are reported as follows: COVID-19 vaccines for 2.3 years compared to Influenza vaccines for 33 years / all other vaccines (except COVID-19) for 33 years. Cardiomyopathy: 683/54/209. Cardiac arrhythmia: 19,241/272/875. Myocarditis: 17,161/149/667. Myocardial infarction and other conditions indicating ischemic heart disease: 10,407/515/1,614. PRR (95% confidence intervals) were reported on four COVID-19 vaccine AE's compared to that of all other vaccines or to that of the Influenza vaccines, respectively: Cardiomyopathy PRR=181 (109-301) and PRR=46.9 (29.8-73.5); Cardiac Arrhythmia PRR=1015 (654-1575) and PRR=316 (206-484); Myocarditis PRR=1652 (1051-2598) and PRR=369 (240-567); Myocardial Infarction and ischemic heart disease PRR=49.0 (31.8 – 75.6) and PRR=15.6 (10.2 – 24.0). All p values < 0.0001.

Conclusions: In all 4 cardiovascular conditions, the rate of AEs reported after COVID-19 vaccines compared to that of the Influenza vaccines or to that of all other vaccines (except COVID-19) were significantly higher ($p < 0.0001$). These data indicate COVID-19 vaccines are associated with markedly elevated cardiovascular risk supporting calls for global market withdrawal of these products and their booster.

INTRODUCTION

Sir Karl Popper believed that scientific knowledge is provisional and refutes the "positivist account of the scientific method" to be replaced by the "induction with falsification principle" [1]. By using observations, as Popper stated that science progresses by falsification and refutation of reigning scientific narratives. Many experienced clinicians have observed a substantial increase in cardiac diseases since the roll out of the COVID-19 vaccines. This prompted a targeted search of the CDC/FDA VAERS database for 4 conditions including cardiomyopathy, cardiac arrhythmia, cardiomyopathy, and myocardial infarction/ischemia. The purpose of this study is to determine if there is a danger signal for any of these conditions using the governmental database using methods CDC/FDA recommend.

METHODS

The US CDC and FDA VAERS was used to extract the data with the MedAlerts.org platform. The following conditions were abstracted for each of the following in MedAlerts.org under "symptoms" (also referred to hereafter as AEs) involving the following cardiovascular conditions.

Cardiomyopathy ('cardiomyopathy acute', 'cardiomyopathy alcoholic', 'cardiomyopathy neonatal');

Cardiac arrhythmia ('arrhythmia', 'arrhythmia neonatal', 'arrhythmia supraventricular', 'arrhythmic storm', 'arrhythmic right ventricular dysplasia', 'arrhythmic dysplasia', 'cardiac fibrillation', 'cardiac flutter');

Myocarditis ('carditis', 'myocarditis', 'myocarditis infectious', 'myocarditis mycotic', 'myocarditis post infection', 'myocarditis septic');

Myocardial infarction ('myocardial infarction', 'other markers of cardiac ischemia').

Using the AEs above, VAERS was analyzed from January 1, 1990 through May 5, 2023 thus yielding

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2.3 years of COVID-19 vaccine data and 33 years for all other vaccines (including Influenza). The preferred methods of analytics were used according to the FDA/CDC/VAERS with what is historically considered a "safe vaccine" compared to that of the novel vaccine thus providing a PRR also referred to as a risk ratio. The COVID-19 vaccines (AEs) were compared to the AEs of the Influenza vaccines and to AEs of all other vaccines except COVID-19 vaccines. According to CDC's Standard Operating Procedures for COVID-19, a two-fold increase in reporting is a sufficient signal to be concerned [2]. Standard statistical methods were used including reporting ratios and 95% confidence intervals using the MedCalc statistical software [3]. A previous publication used identical analyses and included a PRR based not only upon AEs/time as in this investigation, but also included AEs/inoculation and AE's/individual vaccinated utilizing Poisson distribution and Monte Carlo Simulations [4]. The analytics of the AE/inoculation and AE/individual vaccinated are not included in this report because the results obtained were nearly identical to that of the AE/time, and therefore these analytics are unnecessary.

RESULTS

Cardiomyopathy

A total of 892 cases of cardiomyopathy were reported in VAERS as of May 5, 2023. Of those, 683 were reported for the COVID-19 vaccines, 54 were reported for the Influenza vaccines and 209 were reported for all other vaccines except COVID-19 (including the Influenza vaccine) as presented in Table 1 and Figure 1.

Cardiac Arrhythmia

A total of 20,116 cases of cardiac arrhythmia were reported in VAERS as of May 5, 2023. Of those, 19,241 were reported for the COVID-19 vaccines, 272 were reported for the Influenza vaccines and 875 were reported for all other vaccines except COVID-19 (including the Influenza vaccine) as presented in Table 1 and Figure 2.

Myocarditis

A total of 17,828 cases of myocarditis were reported in VAERS as of May 5, 2023. Of those, 17,161 were reported for the COVID-19 vaccines, 149 were reported for the Influenza vaccines and 667 were reported for all other vaccines except COVID-19 (including the Influenza vaccine) as presented in Table 1 and Figure 3.

Myocardial Infarction and Other Markers of Cardiac Ischemia

A total of 12,021 cases of myocardial infarction and other markers of cardiac ischemia were reported in VAERS as of May 5, 2023. Of those, 10,407 were reported for the COVID-19 vaccines, 515 were reported for the Influenza vaccines and 1,614 were reported for all other vaccines except COVID-19 (including the Influenza vaccines) as presented in Table 1 and Figure 4.

DISCUSSION

This study documents a significant increase in cardiomyopathy, cardiac arrhythmia, myocarditis, and myocardial infarction after COVID-19 vaccination when compared to the Influenza vaccines and even when compared to all other vaccines combined (except COVID-19). This study confirms the clinical observation that there has been an increase in these cardiovascular conditions since the rollout of the COVID-19 vaccines.

A recent study from Israel, one of the most highly vaccinated countries in the world, documented a rate of cardiac arrest increasing by 192% from 2020 to 2021 (3.98 to 7.64 per million) and by 225% from 2021 to 2022 (7.64 to 17.16 per million) [5]. These data show an alarming increase in not only cardiovascular and stroke incidences, but also an increase in death.

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In January of 2024, Hulscher et al published a paper describing a review of autopsy studies to determine a possible connection between the COVID-19 vaccine and myocarditis resulting in death [6]. A total of 28 autopsy cases of fatal myocarditis were identified. Of those, 26 cases demonstrated the only organ system affected was the cardiovascular system, and 2 cases suffered myocarditis as a result of multisystem inflammatory syndrome. Of significant note, 75% of the deaths occurred within one week from receipt of the last COVID-19 vaccination (mean 6.2 days). The authors concluded all 28 cases of fatal myocarditis were causally related to the COVID-19 vaccine.

Buergin and colleagues [7] reported on hospital employees scheduled to undergo mRNA-1273 booster vaccination-associated myocardial injury. They defined this as acute dynamic increase in high-sensitivity cardiac troponin concentration above the sex-specific upper limit of normal on day 3 (48-72 hours) post-vaccination without evidence of an alternative cause. Alarmingly, mRNA vaccine associated myocardial injury was more common than previously thought, being mild and transient. Among the 777 participants, 40 (5.1%, 95% CI 3.7-7.0%) had elevated troponin levels on day 3. Interestingly, in contrast to prior literature, this finding was more frequent in women versus men, and this was attributed to the authors' "active surveillance" of their recruited participants compared to prior studies using a "passive surveillance".

A retrospective case series studying healthy members of the US Military reports 23 military members presenting with acute chest pain or significantly elevated cardiac troponin levels within 4 days of mRNA COVID-19 vaccination [8]. All members met the US Military criteria of "physically fit" and had no prior history of cardiac disease. Of the 23 members presented in this case study, 83% showed abnormal electrocardiography findings.

Massari and colleagues conducted a self-controlled case series using national data on COVID-19 vaccination linked to emergency care and hospital discharge databases from Italy. This study included over 3 million individuals under the age of 40. They found an association of myocarditis/pericarditis with the COVID-19 vaccine, specifically after the second BNT162b2 dose and both doses of mRNA-1273. The authors concluded that mRNA vaccines were associated with myocarditis/pericarditis in the population younger than 40 years with the highest risk after vaccination with mRNA-1273 were in males ages 12 to 39 and in females ages 18 to 29 [9].

Rose and colleagues conducted a similar review of VAERS data to assess myocarditis events in relation to the COVID-19 vaccines [10]. When compared to all vaccines combined over the past 30 years, the authors found the incidence of myocarditis was 223 times higher after the COVID-19 vaccination. 76% of the reports noted emergency care and hospitalization was required and 3% died. The results of this paper demonstrated a higher incidence of myocarditis reported after receipt of the second dose, in males, and individuals under 30 years of age.

Rancourt and colleagues provide the first empirical evaluations of age-stratified risk of death after one vaccine injection which they refer to as the vaccine dose fatality rate (vDFR) [11]. Using national all-cause mortality and vaccine rollout data they find the vDFR to be as high as 1% in India and also in the USA when "vaccine equity" campaigns were applied in high-poverty states. The vDFR is 0.05% in Australia. The vDFR increases dramatically with age for older adults, being exponential with a doubling time of approximately 5.2 ± 0.4 years. As a result, the vDFR is an order of magnitude greater in the most elderly population than the all-population value, reaching 0.6 % for the 80+ years age group in Israel and 1 % for the 85+ years age group in Australia, compared to less than 0.01 % for young adults under age 45.

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Skidmore from Michigan State University in October 2023 published an online survey of COVID-19 health experiences and was conducted to collect information regarding reasons for and against COVID-19 inoculations, including experiences with COVID-19 illness and inoculations by server respondents and their social circles [12]. The survey was completed by 2,840 participants between December 18 and 23, 2021. Those who knew someone who experienced a health problem from COVID-19 were more likely to be vaccinated (OR: 1.309, 95% CI: (1.094-1.566), while those who knew someone who experienced a health problem following vaccination were less likely to be vaccinated (OR: 0.56, 95% CI: 0.461-0.698). With these survey data, the total number of fatalities due to COVID-19 inoculation may be as high as 289,789 (95% CI: 229,319 – 344,319).

In September of 2023 Nakahara and colleagues [13] retrospectively compared the incidence of abnormal PET/CT scans in COVID-19 vaccinated versus unvaccinated in an asymptomatic cohort. The study included 303 nonvaccinated patients with 700 vaccinated patients. The maximum standardized ^{18}F-FDG uptake value was higher in vaccinated patients, regardless of sex or patient age, compared to the corresponding nonvaccinated groups. The increased myocardial ^{18}F-FDG uptake was observed in patients imaged for up to 180 days after their second vaccination. Cardiomyocytes predominantly depend upon free fatty acids as they are a much more efficient energy source than glucose or protein. These findings suggest that COVID-19 vaccination shifted the predominant energy source from free fatty acids to glucose. These observations suggest some degree of global myocardial ischemia could be occurring due to myocardial capillary hemagglutination (micro blood clots) as summarized in a review by Scheim et al [14]. The consequences from myocarditis and cardiomypathic changes after COVID-19 vaccination could be associated with a pandemic of cardiac failure in the future [15].

Our study has all the limitations of spontaneous reported safety events after vaccination. The relative underreporting factors (URF) in VAERS for the Influenza vaccines versus COVID-19 vaccines are unknown. Without knowing the URF, it is assumed to be equal for the various vaccines. The CDC VAERS is a passive data surveillance system. Our data reviewed did not analyze specific event information from the vignettes such as demographics, age, sex, or comorbidities. Additionally, there is an underreporting factor [16, 17] which is currently thought to be in the range of 30-100, therefore the actual number of AEs correlated to the COVID-19 vaccines is unknown [18]. According to Rose, for COVID-19 vaccinates the associated with an under-reporting factor may be as low as (URF) of 21. In a 2021 JAMA study Blumenthal et al [19] noted a URF of 41, by using acute allergic reactions to mRNA COVID-19 vaccines. Rose [20] agrees with the findings of Blumenthal despite having previously calculated a lower value in her earlier work. Regardless, the danger signals demonstrated in this study are well over the threshold proportional risk ratio (PRR) set by the CDC/FDA.

CONCLUSION

COVID-19 vaccines compared to other vaccines are associated with significantly increased and unacceptable risk of cardiomyopathy, cardiac arrhythmia, myocarditis, and myocardial infarction (p,0.0001). These data support calls for a global moratorium on the use of COVID-19 vaccines and their boosters at the present time.

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LISTING OF FIGURES AND TABLES

Figure 1 depicts the PRR by Time for Cardiomyopathy Post COVID-19 Vaccines vs. Other Vaccines. PRR for Cardiomyopathy post COVID-19 vaccine vs Influenza vaccines is 181 (95% CI: 109-301, p < 0.0001) and PRR for Cardiomyopathy post COVID-19 vaccine vs All Other vaccines except COVID-19 is 46.9 (95% CI: 29.8-73.5, p < 0.0001).

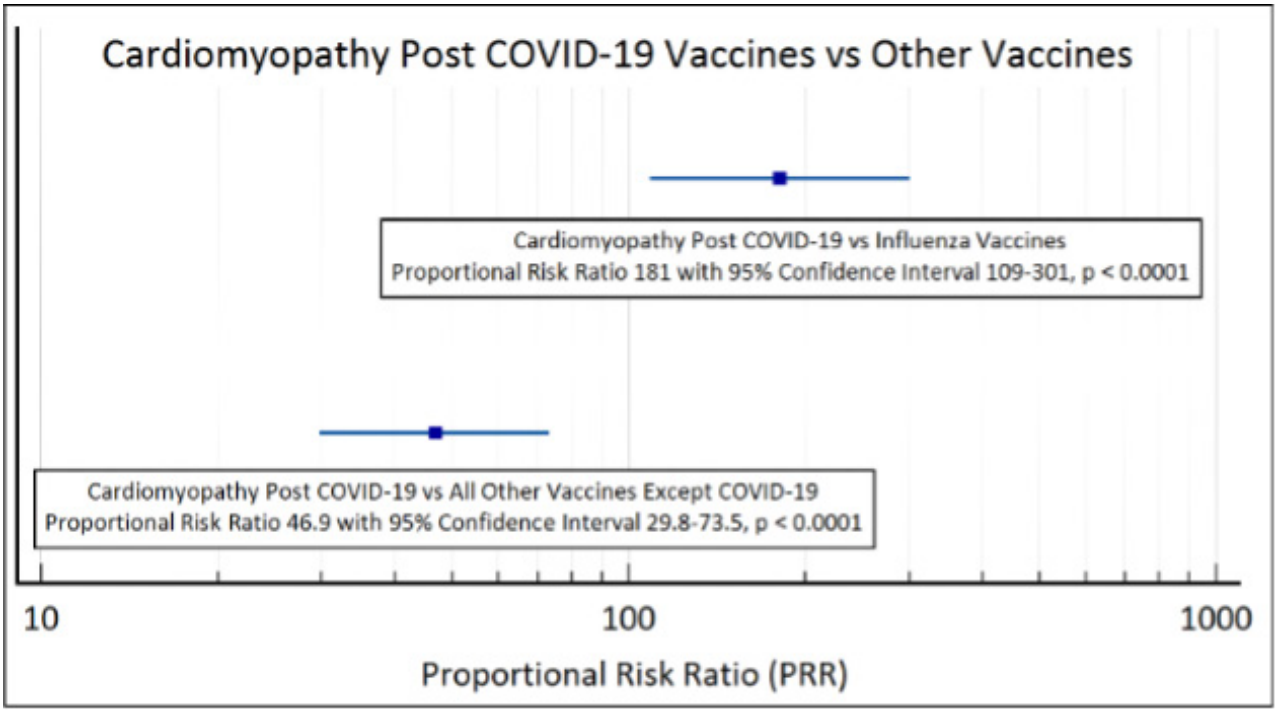

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Figure 2 depicts the PRR by Time for Cardiac Arrhythmia Post COVID-19 Vaccines vs. Other Vaccines. PRR for Cardiac Arrhythmia post COVID-19 vaccine vs Influenza vaccines is 1015 (95% CI: 654-1575, p < 0.0001) and PRR for Cardiac Arrhythmia post COVID-19 vaccine vs All Other vaccines except COVID-19 is 316 (95% CI: 206-484, p < 0.0001).

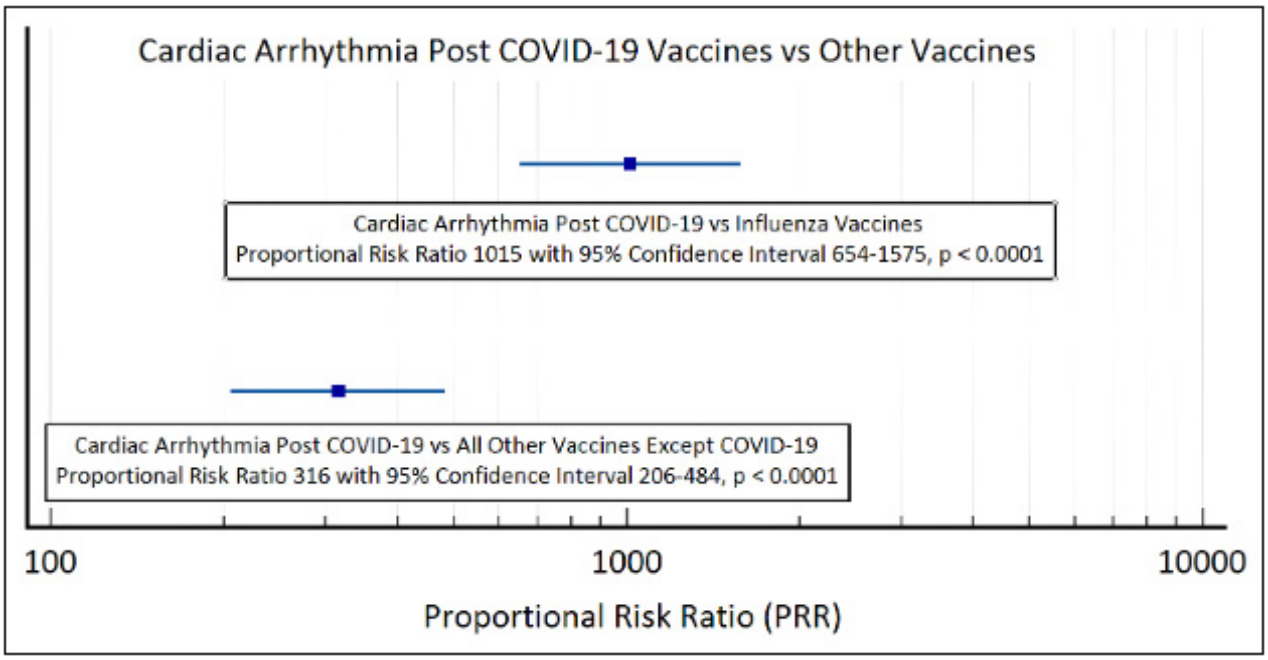

Figure 3 depicts the PRR by Time for Myocarditis Post COVID-19 Vaccines vs. Other Vaccines. PRR for Myocarditis post COVID-19 vaccine vs Influenza vaccines is 1652 (95% CI: 1051-2598, p < 0.0001) and PRR for Myocarditis post COVID-19 vaccine vs All Other vaccines except COVID-19 is 369 (95% CI: 240-567, p < 0.0001).

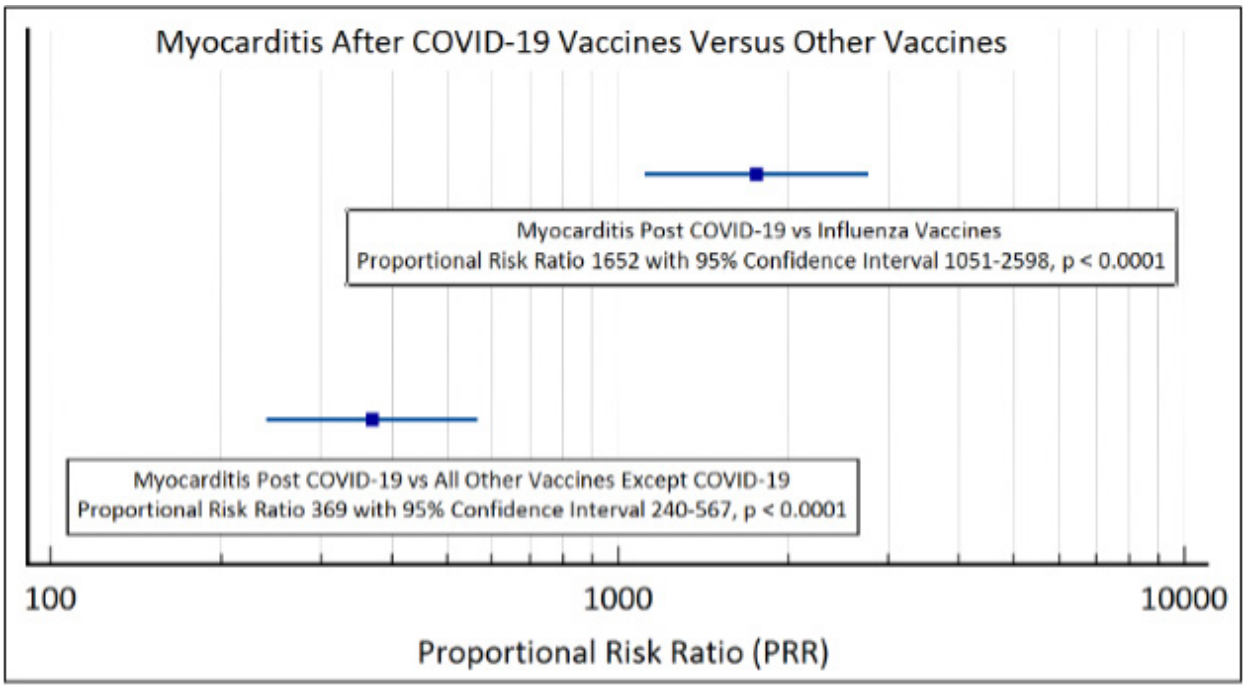

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Figure 4 depicts the PRR by Time for Myocardial Infarction and Other Cardiac Ischemic Events Post COVID-19 Vaccines vs. Other Vaccines. PRR for Myocardial Infarction and Other Cardiac Ischemic Events post COVID-19 vaccine vs Influenza vaccines is 49.0 (95% CI: 31.8-75.6, p < 0.0001) and PRR for Myocardial Infarction and Other Cardiac Ischemic Events post COVID-19 vaccine vs All Other vaccines except COVID-19 is 15.6 (95% CI: 10.2-24.0, p < 0.0001).

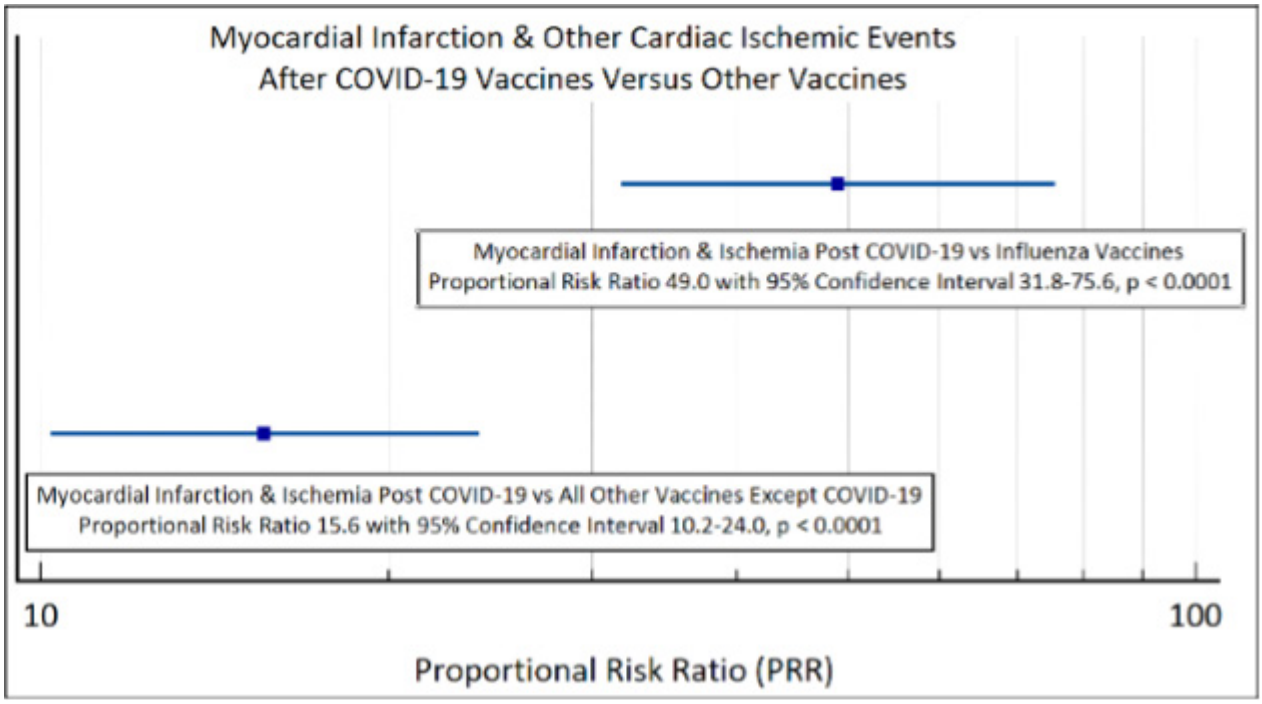

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Table 1 depicts reported Adverse events (AEs) from Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) for COVID-19, Influenza, and All Other Vaccines Except COVID-19 as of May 5, 2023.

Adverse Events (AEs)	Total AEs Reported Jan 1, 1990 through May 5, 2023	COVID-19 vaccine AEs over 2.3 years (28 months)	Influenza vaccine AEs over 33 years	All Other vaccines except COVID-19 (including Influenza vaccine) AEs over 33 years	Risk Ratio by Time (95% Confidence Interval) COVID-19 vaccine vs Influenza Vaccine	Risk Ratio by Time (95% Confidence Interval) COVID-19 vaccine vs All Other Vaccines (including Influenza vax)
Cardiomyopathy	892	683	54	209	181 (109-301)	46.9 (29.8-73.5)
Cardiac arrhythmia	20,116	19,241	272	875	1015 (654-1575)	316 (206-484)
Myocarditis	17,828	17,161	149	667	1652 (1051-2598)	369 (240-567)
Myocardial Infarction and Other Markers of Cardiac Ischemia	12,021	10,407	515	1,614	49.0 (31.8 – 75.6)	15.6 (10.2 – 24.0)

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