

# Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies

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## ABSTRACT

Self-controlled case series (SCCS) is a novel study design uniquely equipped to ethically quantify the safety of vaccination. We sought out to perform a meta-analysis on all SCCS assessing mortality associated with COVID-19 vaccination in the immediate post-vaccination period. We included SCCS investigating the safety of COVID-19 vaccination and reporting all-cause and cardiac-related mortality. Three SCCS were located, totaling approximately 750,000 patients. The pooled hazard ratio (HR) revealed no significant association of COVID-19 vaccination with all-cause mortality (HR = 0.89, 95% CI [0.71, 1.10],  $p = .28$ ). Regarding cardiac-related mortality, the pooled HR suggests that COVID-19 vaccination is associated with an increased risk of cardiac-related mortality (HR = 1.06, 95% CI [1.02, 1.11],  $p = .007$ ). Subgroup analysis showed that the male gender is significantly associated with an increased incidence of cardiac-related deaths (HR = 1.09, 95% CI [1.02, 1.15],  $p = .006$ ). In conclusion, COVID-19 vaccination may be associated with a small increase in cardiac-related mortality, especially among males.

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## Introduction

Severe Acute Respiratory Syndrome/Coronavirus 2 (SARS-CoV-2) vaccination is a crucial prevention method that has helped to control the COVID-19 pandemic. The first such vaccine was licensed by the US Food and Drug Administration (FDA) for emergency use in December 2020.<sup>1,2</sup> Since then, there have been several COVID-19 vaccinations developed with different developmental technologies arising essentially all over the globe, including products from AstraZeneca, Janssen, Sputnik, Pfizer-BioNTech, Moderna, and Sinopharm. Although these vaccines show a great benefit in the prevention of COVID-19 infection and the reduction of hospitalization and mortality rates,<sup>3–5</sup> they have also been associated with many different reported adverse events. Some of the most common of these events include injection site tenderness pain, fatigue, headache, myalgia, and chills.<sup>6–8</sup> More serious events, including severe reactions and even death have been reported.<sup>9–11</sup> Previous studies showed that mRNA vaccines, such as Moderna and Pfizer-BioNTech may be related to myocarditis and myopericarditis in certain patient populations,<sup>12</sup> while other studies have suggested that the ChAdOx1 nCoV-19 vaccine (AstraZeneca) may be associated with an increased incidence of thromboembolic events.<sup>13</sup>

The investigation and assessment of the vaccine safety profile are crucial aspects of any vaccination program.<sup>14</sup> In the case of response to the rapidly evolving COVID-19 pandemic, many vaccines have been approved for emergency usage without full FDA approval, as an appropriate response to the urgent need to protect the at-risk population.<sup>15</sup>

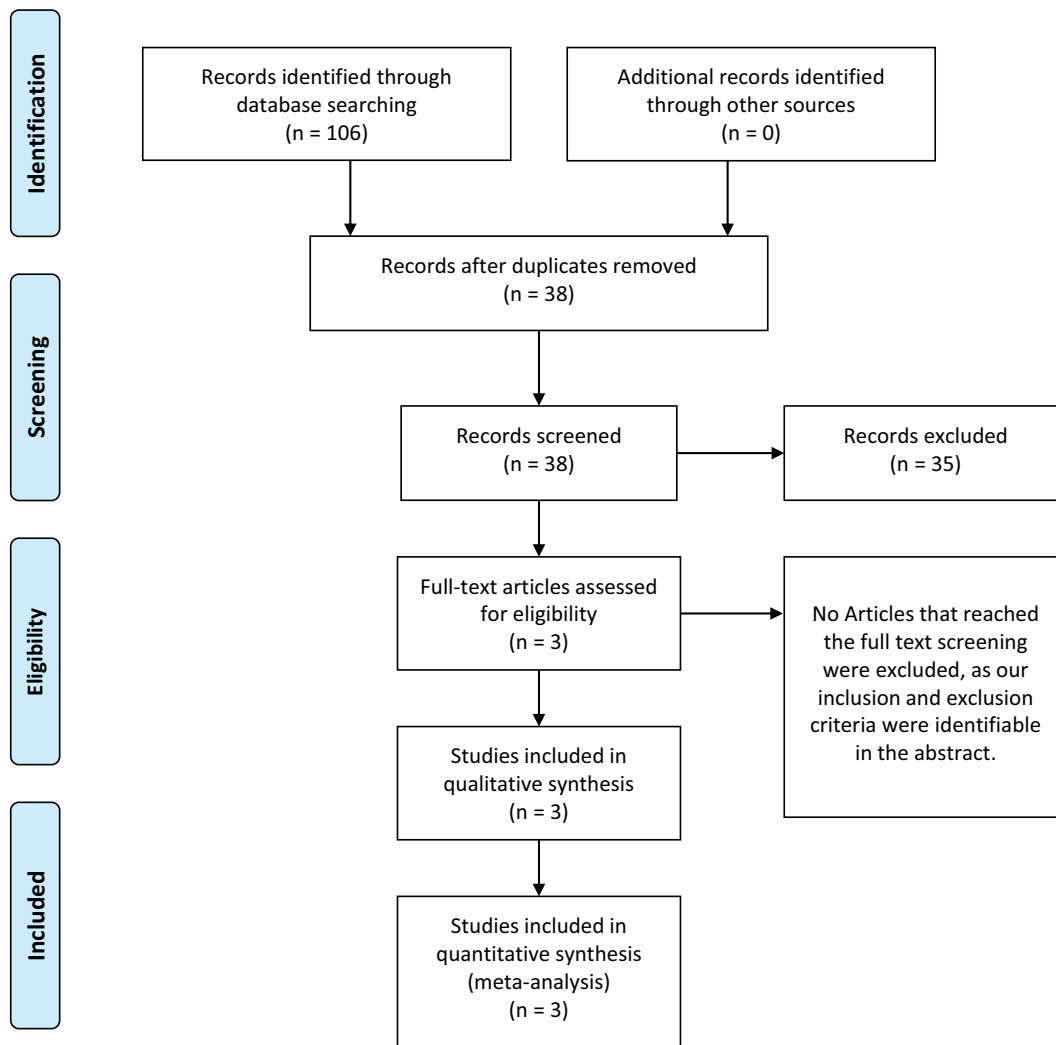
In the presence of such a rapidly changing and dangerous pandemic, purposely exposing patients to the deadly pathogen or wide-scale inoculation with untested vaccination formulations is not feasible secondary to ethical and logistical limitations. Therefore, limited testing prior emergency use authorization was used in almost all cases (15.)

Self-controlled case series (SCCS) is a relatively newly developed study design and statistical methodology that is utilized in evaluating vaccine safety.<sup>16</sup> SCCS is developed to estimate the relative incidence of acute adverse events in a specific period after vaccination which is supposed to be the highest risk period compared to all other times, which represents the control period (observation period). Comparisons are made between the included participants, and only individuals who report the event are included in this study design; thus, participants act as their own control.<sup>17</sup>

In response to a relative wealth of new studies on the topic of COVID-19 vaccine complications in this format, we sought out to perform a meta-analysis of all SCCS studies available on this topic. Our goal was to evaluate the all-cause mortality and cardiac-related mortality risk in the immediate period following COVID-19 vaccination.

## Methods

We performed this systematic review and meta-analysis in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and the Cochrane Handbook of systematic reviews of interventions.<sup>18,19</sup> This study was registered to PROSPERO



**Figure 1.** PRISMA flow chart of the literature search.

with the registration number: CRD42022372256. A PRISMA flow chart of our literature search can be found in [Figure 1](#).

### Eligibility criteria

We included self-controlled case series (SCCS): (1) investigating the safety of COVID-19 vaccination and (2) reporting all-cause and cardiac-related mortality outcomes. The SCCS method is mainly used to evaluate vaccine safety as it calculates the relative incidence (RI) by performing a comparison between the incidence of an event in a specific period that follows exposure (high-risk period) with the incidence during a control period (which is all time in the follow-up period that is not the risk period). The most noted point of strength of the SCCS method is that fixed-time confounders, such as health-related risk factors, are controlled for.<sup>15,16,20</sup>

### Sources

We searched PubMed, Cochrane CENTRAL, Medline, ClinicalTrials.gov, SCOPUS, and Web of Science for published articles that matched our inclusion criteria. We searched

from each database's inception until November 1, 2022, which was the last day of our search.

Ultimately, three self-controlled case studies were included in the final quantitative synthesis, with a total of approximately 750,000 patients. The first case study was performed in the United States, and included residents aged >18 years old receiving COVID-19 vaccination.<sup>21</sup> Included participants were followed up for 25 weeks after vaccination, and the risk period was defined as 28 days post-vaccination. The second study included young people in England<sup>22</sup> followed up for 12 weeks with a risk period defined as the 6 weeks post-vaccination. The third study was conducted in Italy<sup>23</sup> and defined their risk period as the first 30 days after vaccination. Unfortunately, none of the studies included more specific data for deeper analysis of exactly how soon after vaccination events occurred, and which vaccines were involved in these events.

### Data analysis

We extracted outcome endpoints regarding all-cause mortality and cardiac-related mortality. We performed the meta-analysis of this study using Review Manager Software.<sup>24</sup> The effect estimates of the studies were pooled as hazard ratios (HRs)

and 95% confidence interval (CI). Although this meta-analysis was limited to SCCS, as with any meta-analysis, we were extremely concerned about the heterogeneity of the data presented. As a meta-analysis, by definition, includes the combining of data from different performed studies, if that data shows similar results, then the data are homogeneous, and the combination of those studies is considered very strong evidence for the outcome the studies all portray. On the other hand, in cases where studies do not show the same outcomes, those results are considered heterogeneous, and care must be taken to consider why the different studies are showing different results. One example of this is an “outlier” study, which can skew data. We analyzed homogeneous data under the fixed-effects model and heterogeneous data under the random-effects model. We assessed the heterogeneity among studies using the  $I^2$  and the  $p$ -value of the Chi-square tests.<sup>19</sup> Values of  $P < .1$  or  $I^2 > 50\%$  were significant indicators of the presence of heterogeneity. In cases where heterogeneity persists without explanation, the results of the meta-analysis are generally thought to be weaker than an analysis where the heterogeneity can be reduced using accepted strategies, or at least explained by the researchers.

## Results of the meta-analysis

### All-cause mortality

The pooled hazard ratio (HR) revealed no significant association of COVID-19 vaccination with mortality (HR = 0.89, 95% CI

[0.71, 1.10],  $p = .28$ ). Subgroup analysis by age revealed that, in the 18–24 age group, COVID-19 vaccination was not associated with an increased risk of all-cause mortality (HR = 1.04, 95% CI [0.81, 1.35],  $p = .74$ ). The pooled analysis was heterogeneous ( $I^2 = 94\%$ ), as seen in Figure 2a. Heterogeneity was resolved by excluding Stivanello et al.,<sup>23</sup> and homogeneous results still failed to reach significant  $p$  values ( $p = .32$ ), as seen in Figure 2b.

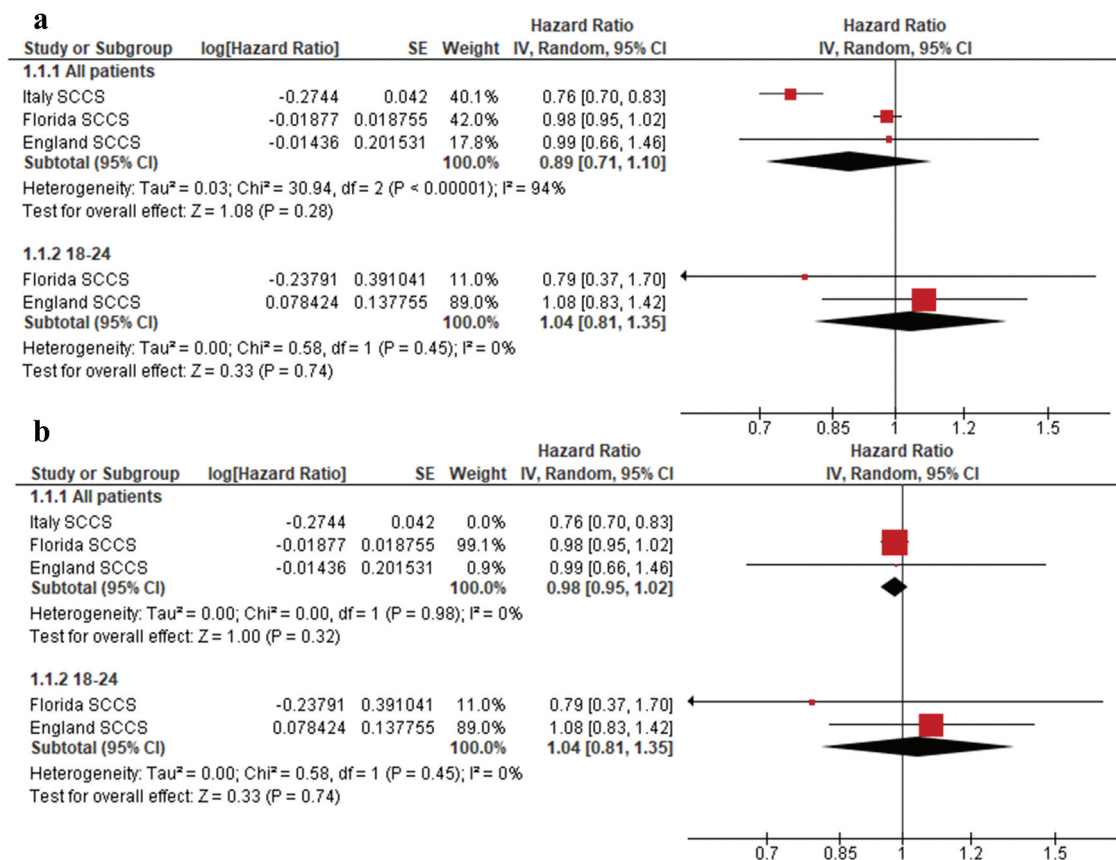
### Cardiac-related mortality

The pooled hazard ratio (HR) suggests that COVID-19 vaccination is associated with an increased risk of cardiac-related mortality (HR = 1.06, 95% CI [1.02, 1.11],  $p = .007$ ). Subgroup analysis showed that male gender is significantly associated with increased risks of cardiac mortality (HR = 1.09, 95% CI [1.02, 1.15],  $p = .006$ ). Subgroups of the female gender and 18–24 age groups showed no significant associations, as seen in Figure 3.

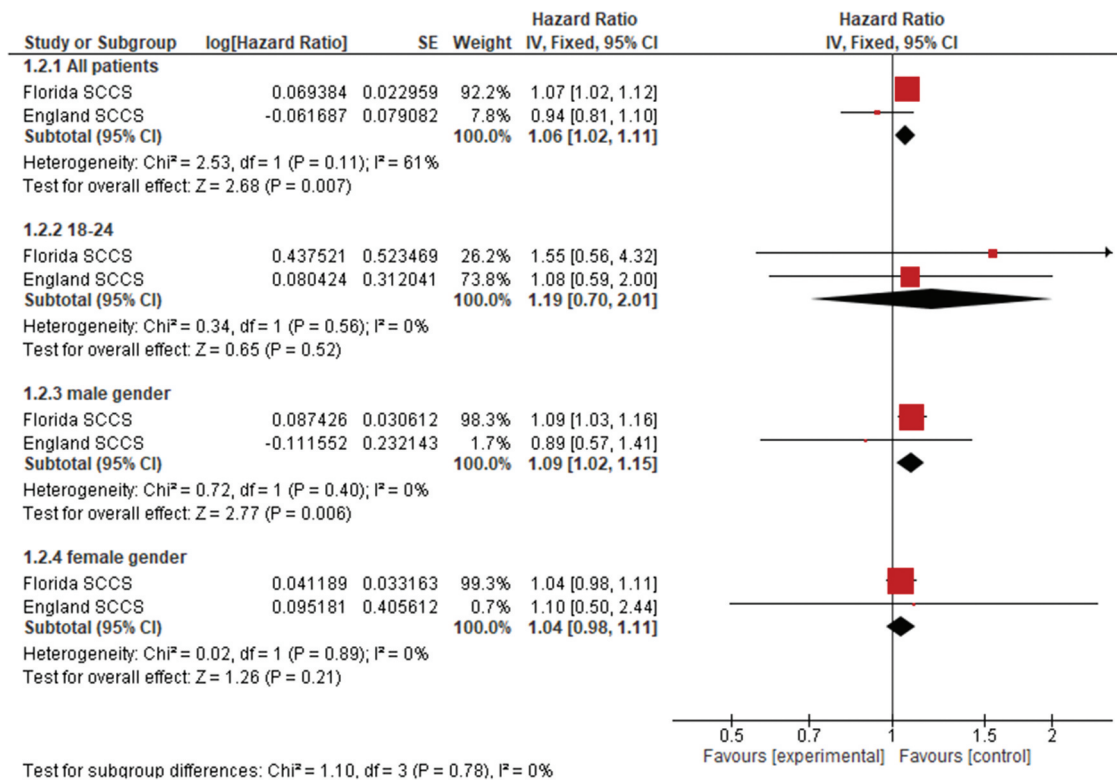
## Discussion

The analysis shows no connection between COVID-19 vaccination and an increased risk of all-cause mortality. However, we found a small, but statistically significant association between the vaccine and cardiac-related mortality. Subgroup analysis was performed to explore the possible risk factors identified male gender as the most important risk factor.

The results are similar to the evidence provided in the literature thus far.<sup>25–27</sup> There is now an increasing body of



**Figure 2.** (a and b) All-cause mortality between the at-risk and control periods. Figure 1a represents the initial analysis, and Figure 1b shows the same analysis after excluding Stivanello et al. to solve the heterogeneity using the “leave-one-out” method.



**Figure 3.** Cardiac-related mortality between the at-risk and control periods, including subgroups by age and gender.

evidence that COVID-19 vaccination does not increase all-cause mortality in large populations. Some examples of this include Bardenheier et al.<sup>25</sup> in 2021 that found that vaccinated residents of nursing homes are significantly less likely to develop vaccine-related adverse events than they were from actual COVID-19 infection. This study went on to show that the risk of mortality was significantly higher in unvaccinated residents than those who received vaccines.<sup>25</sup> Another example includes the cohort study Xu et al.<sup>26</sup> also in 2021, that analyzed mortality from non-COVID-19 causes. Again, lower mortality rates were found in the vaccinated group.<sup>26</sup> Although included in their selected outcomes, they did not find an association with increased cardiac risk, as was shown in our analysis.

The association between COVID-19 vaccination and increased incidences of cardiac-related disorders such as myocarditis has been described by several studies.<sup>12,28,29</sup> Goddard et al.<sup>30</sup> conducted a large study evaluating the incidence of cardiac side effects of the vaccine among 7 million people in the United States. They reported an incidence of 320 cases 1–98 days after approximately 7 million vaccine doses.<sup>30</sup>

Some studies subgrouping by age showed a higher incidence of cardiac side effects in males compared with females. Katsoularis et al. for example, the highest incidence in males aged 18–25.<sup>31</sup> This study also reported an increased risk of myocardial infarction and stroke following actual COVID-19 infection. A large surveillance study on the US vaccinated individuals with myocarditis found that most individuals were considered recovered by healthcare providers after 3 months of the onset of myocarditis and that the outcomes on quality of life were comparable to those in age-matched pre-pandemic populations.<sup>32</sup>

Our findings of increased cardiac-related deaths, especially in males, may have limited clinical utility, as the decision for vaccination should be individualized to each patient. We agree that a patient's primary care physician should take into account each patient's current and past medical history and consideration of each patient's risk of serious disease or death from the virus they are receiving vaccination against. Although we hope this data is helpful in this calculus, we make no other specific recommendations.

As COVID-19 vaccination remains a major political and health concern in the United States, our researchers encountered many opinions, scientific and political, regarding the SCCS produced by Ladapo et al.<sup>21</sup> and published through the Florida Department of Health. We have thoroughly reviewed the opinions and calls for withdrawal from this study, and take these opinions as seriously as we can take any accusation against a data set we have incorporated into one of our reviews. We find no evidence challenging either the validity of the data in Ladapo et al.<sup>21</sup> or challenging the quality or bias of the data set contained therein. As for the interpretation of the data made by that group and their subsequent recommendations, we have no opinion, as our task was to compose a meta-analysis of all SCCS studies on this topic, and we believe we maintain a healthy "arm's length" from these discussions. We have utilized the data and have no evidence that the data are incorrect. Further, we have author consensus that a publication officially produced by a Department of Health in the United States easily meets any reasonable definition of "published and peer reviewed," in the same way that publications from the Center for



Disease Control, (Atlanta, Georgia, USA) are essentially universally seen as such.

As for the strengths of our study, the design is an important factor as limiting our included studies to the SCCS study methodology completely controls for most fixed-time confounders. This methodology also allows for the inclusion of a large sample size, which we have included in this study. In addition to being the first meta-analysis to pool results from only SCCS study designs, another point of strength is that our analysis was very homogeneous.

As far as limitations, the major limitation is that although the studies themselves were quite large, there were a limited number of SCCS studies available for this analysis, at only three. There are also additional limitations inherent to the design of the SCCS study itself. The use of this design in COVID-19 vaccination programs violates the assumption that an event does not affect subsequent exposure (which could be especially true for mRNA vaccines), and this could in theory lead to a source of bias. As there is currently no described tool for assessing the bias inherent to SCCS studies, the authors see the risk of bias as a significant limitation of the present study.

Another major limitation is that the above 60 age group may lead to confounding in cardiac-related mortality. In the Ladapo et al. Study,<sup>21</sup> this group was the majority of all cardiac-related death rates. More importantly, when the authors removed this group from the analysis, the pooled risk incidence (RI) reported no significant association between mortality and COVID-19 post-vaccination (RI = 1.15, 95% CI = 0.99–1.34), mRNA vaccination (RI = 1.17, 95% CI = 1.00–1.37), and males with mRNA vaccination (RI = 1.09, 95% CI = 0.89–1.34).

## Conclusion

The main finding of this meta-analysis is the lack of a connection between COVID-19 vaccination and an increased risk of all-cause mortality, when using all available data from self-controlled case series currently published on this topic. Additionally, in subgroup analysis, we found a statistically significant increase in cardiac-related death, especially in males. These findings, although statistically significant and backed by large sample sizes, were reached by the analysis of self-controlled case series studies, which may invite bias and therefore may be considered a lower level of evidence than analyses of RCTs or cohort trials. Further studies in this area will be necessary to judge the true risk of vaccine-related mortality, and more data will be needed to differentiate precisely which vaccine types and regimens this risk is most related to.

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## Authors' contributions

All authors attest to significant contributions to this work.

## Commitment to diversity

The Marchand Institute remains committed to diversity and tolerance in its research and actively maintains a workplace free of racism and sexism. We proudly state that the authors of this study represent diverse backgrounds and under-represented ethnic groups.

## Consent to publish

Data used was exempt from consent to participate or publish secondary to the nature of the study being a systematic review, retrospectively looking at previously published data.

## Ethics approval and consent to participate

The manuscript has been reviewed by the institutional IRB board at Marchand Institute and was found to be exempt from the IRB review (October 2022). Data used was exempt from consent to participate or publish secondary to the nature of the study being a systematic review, retrospectively looking at previously published data.

## Patient consent

Not applicable to systematic review.

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