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REVIEW ARTICLE

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Concerning Claims that COVID Poses a Greater Risk of Myocarditis than Does Vaccination

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ABSTRACT

A recent Lancet publication by 22 researchers from the British COVID Impact Consortium claimed in their Abstract that COVID-19, the disease, poses a greater childhood risk of cardiovascular injury, including myocarditis, than does the Pfizer mRNA vaccine against COVID. A more clinically relevant question would have been, do vaccinated or unvaccinated children have a greater risk of myocarditis? Though this would have been a simple computation from the data made available exclusively to them, the authors did not report this statistic. Instead, they created a sophisticated model, which generated the answer, buried in Table S16 of the Supplementary Materials: The risk from vaccination is twice as high as the risk from the disease. The authors swapped out the period of interest (the first 9 months of vaccine availability to minors) and compared an earlier time frame for the disease COVID with a later time frame for the vaccine. Thus they were able to generate the answer that they wanted. Though the error bars for these two risk calculations deeply overlap, they reported their result to a compliant press, which was eager to amplify it for public consumption. Data for this study are not available to other scholars for re-analysis.

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COVID-19, Myocarditis risk, mRNA vaccination, Pediatric cardiovascular injury, Vaccine safety.

Introduction

Twenty years ago, Ioannidis [1] documented a phenomenon of irreproducibility, the full implications of which have yet to percolate through the medical establishment. Medical prescribers have no reason to be confident in the literature on which they base their decisions about patient treatments. Posner [2] publicized one reason for the unreliability of peer-reviewed articles in medical journals: the pharmaceutical industry funds the great majority of research concerning drug safety and effectiveness, and their financial interest biases the researchers who depend on them for funding, even when those researchers have appointments in medical schools which are nominally "independent".

Posner was able to discover what he did by comparing pharma-funded research with independent research. But since COVID-19, there is a new trend. Government agencies have control of the largest data sets, an irreplaceable source of information about drug effectiveness and side effects. Since COVID-19, governments are holding this data back or releasing it only to researchers who share the biases of the pharma industry. The published analyses become un-checkable. The worst offender is CDC's Morbidity and Mortality Weekly Reports, which is coasting on a reputation earned in the past. But now, most medical journals are complicit in contributing to this problem, in that they have begun to allow publication of epidemiological studies without requiring that the authors post their raw data to a site where independent researchers can download it to check the published analyses. A 2025 conference panel documented the corruption of Federal regulatory agencies, captured by the drug industry [3].

Critique

Sampri et al. have published a study [4] in response to findings that the mRNA vaccines can induce inflammation of the heart, especially in boys [5-9]. The implied message, delivered implicitly, is that even though the vaccines may, in some cases, seriously compromise the heart, the alternative is to suffer the disease, COVID-19 itself, and the risk of heart damage from the disease is higher than the risk from the vaccines.

This message explicitly contradicts a finding reported only in the Supplementary Appendix, Table S16, that risk from disease is half that of vaccination and statistically consistent with zero when comparison is made for concurrent time frames. The context suggests that the authors swapped out the concurrent time frame and substituted a time frame when they knew that a more virulent COVID variant was circulating for one arm of the comparison.

The Abstract and press release [10,11] are packaged for dissemination to a public that is less scientifically discerning [12,13]. If the claim were made explicitly in a scientific journal, it would draw attention to auxiliary questions that require substantiation:

- What is the probability of an unvaccinated child getting

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the disease compared to a vaccinated child?
- What is the probability of a child avoiding diagnosable COVID-19 because his symptoms are too mild to require medical attention?
- How does the risk of heart damage compare in
- Unvaccinated children who are infected with COVID-19
- Vaccinated children who are infected with COVID-19
- Vaccinated children who are never infected with COVID-19

In summaries for the popular press, a simple dichotomy can be presented: the disease or the vaccine? A peer-reviewed epidemiological study should be required to address the complementary possibilities (vaccination plus disease) and (neither); to assess risk quantitatively for all four cases. The data upon which Sampri et al., relied are easily amenable to address these auxiliary questions, but there is no mention of them in their article.

Sampri et al., acknowledge that there are some patients who had both the vaccine and the infection but the number of these cases is not disclosed. Crucially, the data from which the analysis was conducted are not linked in the Supplementary Appendix, nor has the British National Health Service made them available for other researchers to analyze. Appropriate analysis could provide an answer to the important question: Do children who are infected after vaccination have a higher or lower risk of heart damage than unvaccinated children who are similarly infected? Sampri et al., instead subsume patients who were vaccinated and then infected with unvaccinated patients under a model (not described in detail) for attributing causality that favors the disease, as the more recent event. They explicitly assume without justification that the effects of the vaccine and the effects of the disease are simply additive and do not interact. Exactly how the causative connection is partitioned in this major subset of patients both vaccinated and infected is not clear from the manuscript, but it is a question on which their results depend crucially. Without access to the raw data from which they were working, can we know whether vaccination contributed to heart damage in patients that were infected after vaccination?

The article focuses only on the Pfizer vaccine, but the myocarditis risk from the Moderna vaccine is about three times higher than from Pfizer [14], and in Great Britain, almost a million children received the Moderna shot, easily enough to perform a separate statistical analysis.

At the top of the article in the Findings section of the Summary, the authors find overlapping error bars between the 6-month risk of myocarditis for vaccination vs disease. Their numbers (expressed as risk per 100,000 populations during the given time frame) are 2.24 (1.11 — 3.80) for disease vs 0.85 (0.07 — 1.91) for vaccination. These numbers create a preference for vaccination over disease that is barely significant ($p<0.04$ by my twodimensional calculation of joint probabilities). But hidden in the Supplementary Appendix, Table S16, is a computation which is arguably more relevant, as it is based on the 9-month period when the vaccine was available. For this period — which is directly comparable to the period in which the vaccine was evaluated — the numbers for disease were 0.45 (-0.95 — 2.86) compared to the same 0.85 (0.07 — 1.91) for vaccination. ***The risk from disease is half that of vaccination and statistically consistent with zero. This result was not even mentioned in the text of the article.***

In other results from Table S16, Arterial Thrombotic Events were statistically indistinguishable in vaccinated vs infected children (0.88 vs 1.15); and Inflammatory Conditions were also statistically indistinguishable, with a small difference in the opposite direction (31.5 vs 26.1).

In summary, the message delivered in the Abstract of this article and amplified by the popular press contradicts the computation available only in the Supplementary Materials. In conjunction with this publication, there was a broad campaign of messaging to parents that "Covid jabs trigger FEWER heart problems in children than the virus itself, experts find — amid fears over vaccine's rare side effect." [13]. The proper question for responsible doctors to be asking is whether vaccinated or unvaccinated have a higher overall risk of heart disease. Though the data provided by the UK National Health Service exclusively to these authors would provide an unambiguous answer to this question, the authors chose not to report that answer.

How should data have been analyzed?

Most germane is the all-cause mortality rate pursuant to vaccination — is it higher or lower than a matched group of unvaccinated children? ACM data segregated by vaccination status have been hard to obtain world-wide. I personally have reported on limited data from the British ONS [15] during the short period when they made it available. In this case, the authors had full access to such data, and they chose not to report on the issue that has the most salient clinical implications. Analysis based on Japanese data [16, 17] suggests that a great number of health complications plague those vaccinated with mRNA technology, but the underlying data has, once again, not been made available for independent analysis.

A more limited but still useful analysis would compare rates of myocarditis (and other "vascular and inflammatory diseases") between a vaccinated population and a demographically matched unvaccinated population. Both Pfizer and Moderna vaccines should have been included, especially since the myocarditis risk from Moderna is reported to be three times higher [14]. Sampri et al. had every opportunity to do this.

The more relevant analysis would have compared vaccinated children (Pfizer or Moderna) with unvaccinated children, subsuming the possibilities that there are infected and uninfected subpopulations in both groups. Instead, the authors asked about the relative risks from vaccination vs infection. This question is both less relevant and more ambiguous; less relevant because vaccination is the variable over which public health authorities and parents have some control, more ambiguous because there is a complex interrelation between vaccination status and the incidence and severity of COVID infections, and the effects of vaccination and infection must be separated statistically.

The authors considered only COVID cases that had been diagnosed by a swab test in a medical setting, comprising just 28% of all children during a two-year period. This may have been a small proportion of the actual cases, since almost everyone was exposed during that time, and the disease is extremely contagious, and most children would have had a case too mild to warrant medical intervention.

"In order to study how often people have myocarditis after the virus, you would want to collect everyone who got covid, and see how many get myocarditis. Yet, studies on this topic don't do this. They take people who presented to health care systems and had covid19 and ask how many have myocarditis. But we all know most people who get covid simply recover at home. People who seek medical care are the sickest ones. These studies use a false denominator."

Quote from November, 2025 letter to the FDA-CBER by its director, V. Prasad [18].

The major advantage of this data set is that it is large, comprising 13 million young people. The major disadvantage (for answering the question of relative risk of heart damage from 2 sources) is that most of the cohort had both the infection and the vaccination. There were hundreds of thousands of children who experienced either the COVID vaccination or a COVID diagnosis but not both. This would have provided a clean comparison requiring minimal extraneous assumptions and minimal analysis. But this was not reported, nor was enough information provided in data tables that the reader might perform the comparison.

Another approach would be to address directly the question whether inoculation increased or decreased the risk of heart damage in patients who later suffered a COVID infection. This analysis also was not performed, nor was sufficient information provided in the data tables for the reader to do the calculation.

Given that these two simple and logical choices were eschewed by the authors, the meaning of their results depends crucially on the way that they treated the great majority of subjects who were both vaccinated and infected with the virus. Despite the importance of this detail in the analysis protocol, the text of the manuscript lacked detail in describing how this group was treated.

Summary

First, the authors are asking the wrong question. Most relevant to guide the clinician would be a direct comparison between rates of myocarditis for vaccinated vs unvaccinated children. This simple comparison would subsume the cases of children who are vaccinated and subsequently get COVID anyway, as well as children who are unvaccinated but never get a diagnosable case of COVID. The simple comparison automatically and appropriately includes the likely interaction between vaccination and severity of a subsequent infection. With respect to the latter, the data underlying this study are sufficient to answer whether the interaction between vaccine and viral infection creates greater-than-additive risk or less-than-additive risk. If it is the case that vaccination mitigates the risk of myocarditis from a subsequent case of COVID, this would help buttress the conclusions of the article, and the authors would have been motivated to report this result.

Asking the right question would have been more straightforward, requiring less sophisticated analysis than asking the almost-right question.

Thus it seems that this is a sleight-of-hand for the sake of public relations. The results are reported as both easing parents' concerns about the heart risks associated with the vaccine and also sounding an ominous note about risk of heart damage in case their child is not vaccinated. The authors could have answered the question most relevant to the parents' decision, but chose instead a more difficult and complicated analysis that asks a different question, close enough to fool the news media and the parents' lizard brains.

Second, the analysis does not address the question posed by the authors in the most straightforward way. The straightforward analysis would be to separate two subsets of patients, one group that received the vaccine but were never diagnosed with COVID, the other that were not vaccinated but had a diagnosed case of COVID. Numbers would have been smaller, but the reduced sample size should have been more than adequate to compare these two groups cleanly. What the authors chose to do instead was to introduce the unnecessary (and probably false) assumption that risks from the vaccine and from the disease are purely additive, and to apportion causality according to an opaque, time-dependent model.

The authors chose to look only at the majority of children who were administered the Pfizer vaccine, ignoring the minority who received Moderna. Moderna was reported to pose a far higher risk of myocarditis.

Third, given the (incorrect) question asked and the (incorrect) mode of analysis, the quantitative result they report is inconsistent with the verbally stated conclusion. They report a 95% confidence interval for myocarditis risk from the vaccine as 0.85 (0.07 — 1.91) and for the infection as 2.24 (1.11 — 3.80). Thus the confidence intervals significantly overlap, and they can barely conclude with 95% confidence that for "myocarditis or pericarditis…the risk following vaccination is substantially lower than the risk following infection." From the given error bars, I estimate that the probability that in fact their computed myocarditis risk from the vaccine is actually greater than their computed risk from the disease (but that their means crossed by chance) is 4%, barely statistically significant.

But this comparison, reported prominently in the Article Summary, is offered notwithstanding a contrary result that is only available in the Supplementary Appendix, table S16. For the period that is most comparable to the period when vaccines were given to children, the risk from disease was not 2.24 but only 0.45 (-0.95 — 2.86) — half the risk recorded for the vaccine, and statistically consistent with zero. Promotion of the less relevant result, consistent with government messaging, while concealing the more relevant result which contradicts it appears on its face to be a reporting bias.

In conjunction with this publication, there was a broad campaign of messaging to parents that "Covid jabs trigger FEWER heart problems in children than the virus itself, experts find — amid fears over vaccine's rare side effect." We find that this claim is not supported by the analysis of Sampri et al. We find the regulatory agencies remiss in approving these shots for healthy children in the absence of evidence that there is benefit to overwhelm the acknowledged risk.

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