Benefit risk contextualization of COVID-19 vaccines in the EU

Peer-reviewed author version

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Abstract

Introduction
The main public health priority during the pandemic is maintaining mortality as low as possible and minimising the pandemic induced health and economic distress. To achieve this goal, several vaccines against the SARS-CoV-2 induced COVID-19 disease were developed rapidly, all while adhering to stringent quality, safety, and efficacy standards. COVID-19 vaccines are unquestionably effective, lowering the risk of contracting and spreading the virus, as well as lowering the severity of symptoms thereby decreasing the overall COVID-19 disease burden.

Objective
To propose a method to quantify the benefits and risks of COVID-19 vaccines and to develop a user tool for a benefit-risk assessment of myocarditis, pericarditis and thrombosis with thromboycytopenia (TTS).

Method
Using a probabilistic model to account for differential vaccine effectiveness and temporal differences in disease dynamics, the benefit of different vaccines in the European Economic Area were calculated by comparing the observed number of confirmed cases, hospitalisations, ICU admissions and deaths (source ECDC) with the expected number of these events had no COVID-19 vaccination been available. The myocarditis, pericarditis and TTS risk associated with the vaccines is evaluated by comparing the observed risk events (source EudraVigilance) to the expected events based on background incidence rates of the risk (source EMA). As there is uncertainty and missing information in the background incidence rate estimation, as well as the vaccine coverage, we use multiple imputation for missing information and pooling to join estimates. A Shiny R application was developed for preparedness in upcoming benefit-risk assessments.

Results
In general, when relying on vaccine effectiveness estimates from the literature, the benefit of vaccination is evidenced by the prevention of a total of 13,322,567 confirmed COVID-19 infections, 933,230 COVID-19 hospitalisations, 150,106 ICU admissions and 220,880 COVID-19 related deaths in the European Economic Area, since the start of the vaccination program. These prevented clinical events outweigh the associated risks of each vaccine type in each age category. The risk of myocarditis after Spikevax vaccination is higher than the risk after Comirnaty vaccination, with males having a higher-than-expected risk of myocarditis after Spikevax vaccination < 40 years of age.

Conclusion
This analysis clearly demonstrates that the benefits of COVID-19 vaccination far outweigh the myocarditis, pericarditis and TTS risks. Rare, life-threatening side effects as a result of vaccination might go unnoticed in a clinical trial of conventional size and should be documented, investigated, and alerted as soon as possible after introduction of vaccines into large populations. The proposed methodology can be applied to any serious side effect that may occur in the future.