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Commentary

Risk and Benefits of mRNA Vaccines

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ABOUT THE STUDY

The discovery of the mRNA vaccine against the backdrop of the ominous and unpredictable COVID-19 epidemic brought an adage to life. It shone brightly as the ideal vaccine, with a low risk of side effects and a fast manufacturing process. The most significant side effects include anaphylaxis, antibody-dependent boosts, and fatalities, which occur in small numbers. Temperature control is required for storage and shipping, making it inaccessible to India. The most shocking revelation was the biases in vaccine reporting, which revealed that only the appealingly high numbers of the somewhat equivocal relative risk reduction were disclosed, while the limited figures of the more upfront absolute risk reduction were kept at bay.

The first time an mRNA was used for therapeutic purposes was in 1989, when nanoparticles were used to successfully transfect it *in vitro*. Following the success of *in vivo* mRNA injection, the idea of using it as a vaccine was developed. Due to its efficacious immunological properties, remarkable safety and the advantage of malleability, it promised good candidature for a vaccine. The pandemic's urgency necessitated the development of a vaccine with not just a low risk of side effects, but also a fast manufacturing time. The mRNA vaccine fit the bill just right. The mRNA vaccine, instead of delivering a virus or a viral protein, would deliver genetic information, purporting the host's cells to produce the antigen–engendering the advantages of high biosafety and immune simulation without the risk of potential infection.

Real-world research has shown that mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are successful in avoiding COVID-19 instances, hospitalizations, and fatalities since their approval. In the United States, however, increased incidences of myocarditis and pericarditis (inflammation of the heart or its lining) have been associated to mRNA COVID-19 immunisation, particularly in male teens and young adults. Food and Drug Administration conducted a benefit-risk assessment to inform regulatory decisions related to the Biologics License Application (BLA) for use of CVmRNA among ages 16 years and older. The evaluation followed a defined Benefit-Risk Framework (BRF) with four dimensions: analysis of condition, current treatment options, benefits, risks, and risk management. Considering the different clinical implications of hospitalization due to COVID-19 infection versus vaccine-attributable myocarditis/pericarditis cases, we determine the benefits still outweigh the risks even for this high-risk subgroup.

The urgent need for a vaccine to prevent infection and control the pandemic, the lack of information, and the ambiguity around vaccine effectiveness and adverse effects are all factors to consider. The benefit endpoints considered in this benefit-risk assessment include preventable COVID-19 cases, hospitalizations, ICU admissions, and deaths. These criteria were chosen because they are the most explicit, trackable, and quantitative results with the greatest public health impact. The increase of myocarditis/pericarditis post-vaccination was considered as a key risk post COVID-19 vaccination due to its potentially severe consequences. The benefit-risk assessment is an iterative process. We may need to reassess the benefits and risks of the vaccine in the future if the pandemic slows down or if the emergence of a new variant leads to significant reduction of vaccine efficacy.

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