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COVID-19 vaccination in autoimmune disease (COVAD) survey protocol

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Abstract

The coronavirus disease-2019 (COVID-19) pandemic continues to be a cause of unprecedented global morbidity and mortality. Whilst COVID-19 vaccination has emerged as the only tangible solution to reducing poor clinical outcomes, vaccine hesitancy continues to be an obstacle to achieving high levels of vaccine uptake. This represents particular risk to patients with autoimmune diseases, a group already at increased risk of hospitalization and poor clinical outcomes related to COVID-19 infection. Whilst there is a paucity of long-term safety and efficacy data of COVID-19 vaccination in patients with autoimmune diseases, the current evidence strongly suggests that the benefits of vaccination outweigh the risks of adverse effects and disease flares. Herein, we report the protocol of the COVID-19 Vaccination in Autoimmune Diseases (COVAD) study, an ongoing international collaborative study involving 29 countries and over 110 investigators.

Keywords COVID-19 · Autoimmune diseases · COVAD · Vaccination · Survey

Introduction

The ongoing coronavirus disease-2019 (COVID-19) global pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to cause unprecedented morbidity and mortality, with even the most robust healthcare systems struggling to deliver consistent high-quality care to patients with COVID-19, and the effects on other functions of the healthcare system. The only tangible way to reduce the socioeconomic burden and strain on healthcare systems due to COVID-19 is to achieve herd immunity against SARS-CoV-2 [1, 2]. In this respect, vaccination provides a ray of hope as a powerful tool for reducing the adverse outcomes of COVID-19. Current evidence suggests that patients with systemic autoimmune rheumatic diseases (AIRD) are at an increased risk of severe COVID-19 clinical outcomes, emphasizing the importance of COVID-19 vaccination in this patient group [3]. However, a high degree of vaccine hesitancy continues to be a hurdle against vaccination in patients with autoimmune disease as well as in healthy individuals.

The exclusion of patients with AIRD from COVID-19 vaccine trials inevitably resulted in lacunae in the evidence about the long-term safety and efficacy of COVID-19 vaccination. There were also concerns about the efficacy of using COVID-19 vaccines in patients on immunosuppressive drugs and whether or not to stop medication. This unsurprisingly gave rise to fears of disease flares and adverse effects associated with vaccination in an already vulnerable group, amongst patients and healthcare professionals, increasing vaccine hesitancy [4, 5]. The unprecedented disruption to the healthcare delivery system, most prominently the closure of many outpatient clinics due to their conversion to COVID-19 wards and redeployment of the staff, as well as the marked reduction in elective and preventive hospital visits by patients due to the imposition of travel restrictions, coupled with the advent of mainstream telemedicine services, had an inescapable effect on medical research [6]. The pandemic also had a positive effect of bringing together

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clinicians and researchers from around the world, united by the common goal of improving patient care, catalysing an increase in global networking for research [7].

To address the gaps in the current evidence, a global study group of doctors and researchers conceptualized the COVID-19 Vaccination in Autoimmune Diseases (COVAD) study, with the vision of collecting meaningful data on the post-vaccination adverse effects and their determinants in patients with AIRD, particularly patients with rare conditions such as idiopathic inflammatory myopathies, systemic sclerosis and other systemic autoimmune diseases assessing these effects in comparison to those observed in people without AIRD. The COVAD study is a long-term ongoing global patient self-reported survey study, with the goal of evaluating the long-term efficacy, as well as the short and long-term adverse effects and disease flares in AIRD patients vaccinated against COVID.

Methods

We developed an extensive self-report e-survey to assess the safety of the COVID-19 vaccine in idiopathic inflammatory myopathies and other AIRDs, and non-autoimmune controls. The questionnaire was vetted by international experts, pilot tested, validated and translated into 18 languages, before being hosted on the surveymonkey.com platform. Back and forth translations were performed by two independent reviewers per language. The survey questions were designed to evaluate previous COVID-19 infection, current vaccination status, and short-term (within 1–2 weeks) as well as long term (1–12 months) adverse drug effects following vaccine administration.

Literature review

A search was conducted using PubMed, MEDLINE, EMBASE, and SCOPUS databases, using the combination of the keywords "COVID-19 OR SARS-CoV2 OR SARSCOV-2 OR novel coronavirus OR nCOV" AND "vaccination OR vaccine OR immunization OR immunization" AND "autoimmune disease OR AID OR rheumatic disease OR autoimmune inflammatory rheumatic disease OR AIRD" AND "side effect OR adverse effect OR adverse reaction". Additional searches were performed with the terms "signs OR symptoms OR effects OR features OR clinical features OR clinical characteristics". Approximately, 2300 articles were identified and ranged from case reports, case series, and letters to the editor, and observational studies to narrative reviews and systematic reviews. Relevant articles were independently reviewed and used to formulate the survey questionnaire. Initially, 34 questions were generated. The questions "Who confirmed your autoimmune disease diagnosis?" and "In which year were you were diagnosed with autoimmune disease?" were added, as well as questions regarding details of symptoms including "What kind of rashes did you notice?" and "If you have swelling in your joints, how many joints are swollen". Two questions regarding contact details including telephone number and email were excluded to preserve patient anonymity. Finally, there were 36 questions. Core item set included demographics, post-vaccination adverse effects symptom set as per standard CDC guidelines, and patient-reported outcome measures.

Survey design

The baseline questionnaire featured 36 Covid-19 and AIRD-related questions, covering several areas including previous COVID-19 infection ($n=5$), vaccination status ($n=5$), short-term minor and major adverse effects ($n=2$), diagnosis and current symptom status ($n=11$), functional status ($n=3$), treatment history ($n=6$) and demographics ($n=4$). Fifteen were multiple choice questions requiring a single answer option, while nine questions could have multiple answer options selected, three questions needed an answer to be selected from a drop-down list, two questions asked the respondents for a specific date or for a specific number of days, two questions asked the respondent to answer on a self-reporting scale, two were questions with five components each to be reported on a 5-point Likert scale, and two asked for contact details for follow-up. Choices closed ended in 24 questions with an "other (please specify)" option were deemed appropriate in 13 questions. The survey was designed by LG, reviewed by RA, and was translated into 18 languages. The survey is enclosed as Supplementary file 3. Data dictionary is provided as Supplementary file 4.

Pilot testing and validation

Four rheumatologists (RA, LG, VA and HC), one neurologist (JBL), and one undergraduate medical student (VA) reviewed the questions and confirmed them to be representative of the content and face validity. The questionnaire underwent extensive pilot testing with 50 rounds of dummy completions with 25 people to identify errors in wording grammar, and syntax, and critically evaluate face validity. 26 questions were either modified, added or deleted following pilot testing. The average survey time was 5 minutes. A logic function was applied in five questions to limit survey time. The respondents could change the answers before submission but not after it. All questions, except the two asking for contact details, were mandatory.

Population selection

Participants were eligible to participate if they are were adults (> 18 years old), and either healthy, or diagnosed to have any autoimmune disease. Convenience sampling was used, and all those who agreed to participate were included in the survey. A brief explanation was provided in the cover letter obtained by clicking the survey link, which include details of the survey purpose, content, data handling, and investigator. It also sought informed consent for publication of results in a peer-reviewed journal.

The study was not specifically advertised as a study of vaccine hesitancy, thus minimizing bias by attracting people with strongly held views on the matter. No incentives were offered for survey completion.

Consent and ethics approvals

Informed consent was obtained at the beginning of the survey and no incentives were offered for survey completion. Approval of local institutional ethics committee was obtained as per local guidelines [8]. We adhered to the Checklist for Reporting Results of Internet e-surveys to report the data [9, 10] with electronic protocols to address checks were done to avoid duplicated responses from a single respondent.

Survey dissemination

An international group of 110 rheumatologists, internists, neurologists and immunologists from > 80 healthcare centers in over 50 countries conducted the e-survey with their patients and their non-AIRD family members. In addition, the survey was floated on social media platforms (e.g. WhatsApp, Facebook, and Instagram) and among online patient support group members across the world. The survey was first launched in the first half of 2021 and shall be open until the 31st of December 2021. As of August 2021, 16,327 responses had accrued. We retrieved the hesitancy data from the baseline survey. Future surveys would be designed based on the same model and address concerns around long-term effects on disease and physical function, booster shots and breakthrough infections, and other issues arising after of COVID-19 vaccination.

Statistical analysis

Descriptive statistics would be used. Intergroup comparisons would be made as required by the research question. Open-ended responses in the "Others (please specify)" category would be manually allocated to existent categories, and a new category would be listed when the responses did not fit into an existent category. Data will be downloaded from surveymonkey.com into Microsoft Excel for analysis. Incomplete responses would be excluded at the time of analysis. Stata, R and SPSS would be used for future analysis.

Future analyses from the dataset

The anonymized dataset would be open to future analysis by the core team based on proposed hypothesis, research question and study design proposed by collaborators. A COVAD steering committee has been proposed to vet the proposals for scientific validity and feasibility. Relevant authorship guidelines have been formulated to this effect. A study request form has been devised to detail the research question, methods, data variables to be analysed, geographic region and time period of study, and proposed statistical analyses (Supplementary file 3).

Dissemination of outcomes

Results will be disseminated in peer-reviewed journals, via the media, online, and at academic conferences. A plain language summary of results from the study will be made available to participants upon request.

Future research and data sharing

Participants are invited to provide a unique identifier code with optional consent to be contacted for future research, such as further follow-up beyond 6 months. All information about the study (including design, project administration, and publication preprints) will be available on request [11].

Project closure

At the conclusion of the study, recruitment materials, the project landing page, and online survey materials will be deactivated or removed. All data will remain securely stored with PI for a period of 5 years.

Discussion

There is certainly an unmet need for further research into the long-term safety and efficacy of COVID-19 vaccination in patients with AIRD (24). The prospective design of the project is designed to provide timely information to federal and regulatory agencies regarding the emergent concerns around vaccination among individuals with autoimmune disease. This information will be useful to inform the development of relevant practices and screening tools to identify those at utmost risk of adverse events. It may also provide

insight into the effect of current immunosuppressant use on the risk for adverse events, and potentially guide vaccine administration and even management post-vaccination based on immunosuppression level and disease-specific stratified risk sets. While the format of the study is a self-reporting survey, the addition of specific questions regarding verification of diagnosis of autoimmune disease by a healthcare professional"Who confirmed your autoimmune disease diagnosis?" as well as most respondents being patients with chronic AIRDs, who, with their familiarity of their condition and treatment, would be more likely to correctly report symptoms, adverse effects and treatment history, increases the validity of the data collected. The databank would provide further insights into risks incurrent by age, gender, ethnicity, and vaccine type, if any, which may be useful in refining more targetted vaccination approaches towards particular vulnerable groups and specific regions. Most importantly, this large ethnically and geographically diverse dataset will add to the valuable databank of information on the safety of COVID vaccines and curb misinformation [12, 13].

Furthermore, the findings of this research can guide policymakers on the various aspects of immunization that may be focussed on in future research to reduce imminent risks of immediate adverse events, short- and long-term side effects, and most importantly triggered autoimmunity in specific AIDs, and relevant groups such as pregnant and lactating women [14]. The COVID-19 pandemic has widened the communication gap between care providers and patients, and it is imperative to understand patient perspectives as gathered by this self-report survey. Finally, the findings from this study can be used to devise well-informed guidelines for families on how to deal with this unique situation to improve care and quality of life among people with AIDs whilst protecting them from imminent risks of contracting COVID-19.

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Declarations

Conflict of interest OD has/had consultancy relationship with and/or has received research funding from or has served as a speaker for the following companies in the area of potential treatments for systemic sclerosis and its complications in the last 3 years: Abbvie, Acceleron, Alcimed, Amgen, AnaMar, Arxx, Baecon, Blade, Bayer, Boehringer Ingelheim, ChemomAb, Corbus, CSL Behring, Galapagos, Glenmark, GSK, Horizon (Curzion), Inventiva, iQvia, Kymera, Lupin, Medac, Medscape, Mitsubishi Tanabe, Novartis, Roche, Roivant, Sanofi, Serodapharm, Topadur and UCB. Patent issued "mir-29 for the treatment of systemic sclerosis" (US8247389, EP2331143). The rest of the authors have no COI relevant to this manuscript.

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Disclaimer No part of this manuscript has been copied or published elsewhere in whole or in part.

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