INPLASY PROTOCOL

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None declared.

Inflammatory myopathy following coronavirus disease 2019 vaccination: a systematic review

Ding, YK[1]; Chen, XX[2]; Ge, YP[3].

Review question / Objective: **Reports of unexpected side effects have accompanied the vaccination of larger proportions of the population against coronavirus disease 2019 (COVID-19), including a few cases of inflammatory myopathy (IM). In a bid to improve understanding of the clinical course of vaccine complications, a systematic review of reported cases of IM following COVID-19 vaccination has been conducted.**
Condition being studied: **Safety concerns have surrounded the vaccines since their development, with common adverse effects including local reaction at the site of injection and diverse non-specific flu-like symptoms (9). Most symptoms occur soon after vaccination and resolve within a short period but some serious events such as myopericarditis and cerebral venous thrombosis post COVID-19 vaccination had been reported. Meanwhile, some rare cases of vaccine-associated IMs have been reported. The current study systematically reviewed IM cases reported post-COVID-19 vaccination to date. Clinical and laboratory features are described and therapy and prognosis discussed.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 September 2022 and was last updated on 18 September 2022 (registration number INPLASY202290084).

INTRODUCTION

Review question / Objective: **Reports of unexpected side effects have accompanied the vaccination of larger proportions of the population against coronavirus disease 2019 (COVID-19), including a few cases of inflammatory myopathy (IM). In a bid to improve understanding of the clinical course of vaccine complications, a systematic review of reported cases of IM following COVID-19 vaccination has been conducted.**

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METHODS

Participant or population: Patients with inflammatory myopathy after COVID-19 vaccination.

Intervention: Not applicable.

Comparator: Not applicable.

Study designs to be included: Followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement.

Eligibility criteria: The study was undertaken to systematically review IM patients followed with COVID-19 vaccination. A PICOS acronym was used to formulate the questions for this study: (1) participants (patients with IMs), (2) intervention or exposition (COVID-19 vaccination), (3) comparison or control (not applicable), (4) outcomes measures (time, dose and type of COVID-19 vaccination), (5) types of studies included (case reports and series of cases).

Information sources: PubMed and Embase.

Main outcome(s): COVID-19 vaccine manufacturers were reported by 21 studies including 34 patients as follows: 21 (61.8%) received Pfizer/BioNTech (BNT162b2); 7 (2o.6%) Oxford-AstraZeneca (AZD1222, ChAdOx1); 4 Moderna (mRNA-1273); 1 Janssen and 1 Sinovac Biotech (CoronaVac) vaccines. Thirty-four patients reported the interval between vaccination and symptom onset with 18 (52.9%) patients developing symptoms after the first dose of CoV-19 vaccine and 16 (47.1%) after the second dose. Furthermore, 14/18 (77.8%) patients developed symptoms within 2 weeks of the first dose and 15/16 (93.8%) within 2 weeks of the second dose. Overall, 29/34 (85.3%) patients developed myositis symptoms within 2 weeks of the first or second dose of the COVID-19 vaccine.

Quality assessment / Risk of bias analysis: The risk of bias for each included study was assessed using the Joanna Briggs Institute Critical Appraisal checklist for case reports and case series. Disagreements were solved between the two investigators by consensus or by another independent investigator.

Strategy of data synthesis: Two independent investigators systematically searched PubMed and Embase to identify relevant studies published up to July 2022. We searched Medical Subject Headings terms and keywords in multiple combinations, including COVID-19 or SARS-CoV-2 vaccine, dermatomyositis, myositis or inflammatory myopathy.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Country(ies) involved: China.

Keywords: inflammatory myopathy, dermatomyositis, coronavirus disease 2019 vaccine, SARS-COV-2 vaccine

Contributions of each author:
Author 1 - Yukang Ding - Data curation; Formal analysis.
Author 2 - Xixia Chen - Analyse the data.
Author 3 - Yongpeng Ge - Data curation; Methodology; Writing – review & editing.
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