

INPLASY PROTOCOL

New-Onset Inflammatory Arthritis After Covid-19 Vaccination

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None declared.

Review question / Objective: Investigate the new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases and analyze their clinical patterns.

Condition being studied: To help the readers to understand the clinical patterns of new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases.

Eligibility criteria: Inclusion criteria: publications of new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases between January 2020 to March 2022. Exclusion criteria: cases with arthritis after SARS-CoV-2 infection and arthritis reactivation in those with underlying or history of arthritis-associated or autoimmune diseases.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 July 2022 and was last updated on 31 July 2022 (registration number INPLASY202270128).

INTRODUCTION

Review question / Objective: Investigate the new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases and analyze their clinical patterns.

Rationale: Few messages were found about the new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases.

Condition being studied: To help the readers to understand the clinical patterns of new-onset inflammatory arthritis after

Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases.

METHODS

Search strategy: We searched for the case reports, case series, observation studies, cohort studies, and systematic review of new-onset arthritis after Covid-19 vaccination via Medline (PubMed), Embase, and Web of Science. Due to the initiation of Covid-19 outbreak and vaccines development in late-2019 and mid-2020 respectively, we set the date of publication between January 2020 to March 2022. Keywords including “arthritis”, “arthralgia”, “Covid-19 vaccine”, and “SARS-CoV-2 vaccine” were adopted with Boolean algebra and MeSH term. To emphasize the “new-onset” arthritis contributed from “Covid-19 vaccines”, studies about arthritis after SARS-CoV-2 infection, and arthritis reactivation in patients with underlying or history of arthritis-associated and other autoimmune diseases, were excluded for afterward analysis.

Participant or population: All patients with new-onset inflammatory arthritis after Covid-19 vaccination.

Intervention: Not applicable.

Comparator: Not applicable.

Study designs to be included: Clinical characteristics including diagnosis, age, gender, vaccine types, time interval between events, joints involvement (poly- or oligo-/monoarthritis), and laboratory data reflecting inflammatory status were sorted and p values between these parameters are calculated with independent sample Student's t-test or 2x2 Fisher's exact test.

Eligibility criteria: Inclusion criteria: publications of new-onset inflammatory arthritis after Covid-19 vaccination in patients without pre-existing autoimmune nor rheumatic diseases between January 2020 to March 2022. Exclusion criteria: cases with arthritis after SARS-CoV-2

infection and arthritis reactivation in those with underlying or history of arthritis-associated or autoimmune diseases.

Information sources: Medline (PubMed), Embase, and Web of Science.

Main outcome(s): Among 39 cases with new-onset post-vaccination arthritis including 25 females and 13 males (1 unknown), the most common diagnosis is adult-onset Still's disease (AoSD, 10 cases), and the most common vaccine types are BNT162b2 (16 cases) and AZD-1222 (or ChAdOx1-nCoV19, 15 cases). Sub-analysis reveals that postvaccination polyarthritis is more common among female (p value = 0.016, by 2x2 Fisher's exact test, compared with male patients) and older patients (p = 0.006, by Student's t test).

Additional outcome(s): The C-reactive protein (CRP) level is significantly higher in cases with postvaccination inflammatory polyarthritis than oligoarthritis (p = 0.029), as well as in cases with AoSD than other causes of post-vaccination arthritis (p = 0.004). The serum level erythrocyte sedimentation rate (ESR) in patients with post-vaccination AoSD are independent on other clinical variables in the analysis.

Quality assessment / Risk of bias analysis: Following the checklist of Joanna Briggs Institute (JBI) Manual for Evidence Synthesis of case reports and case series.

Strategy of data synthesis: Student's t-test or 2x2 Fisher's exact test.

Subgroup analysis: Diagnosis of arthritis, age, gender, vaccine types, time interval between vaccination and arthritis onset, joints involvement (poly- or oligo-/monoarthritis), and laboratory data of blood leukocyte count, serum CRP and ESR.

Sensitivity analysis: p < 0.05 is considered significant.

Language restriction: English.

Country(ies) involved: Taiwan.

Keywords: Coronavirus disease 19 (Covid-19), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), vaccine, inflammatory arthritis.

Dissemination plans: To be submitted to "International Journal of Rheumatic Diseases".

Contributions of each author:

Author 1 - Cheng-Che Chen - Study designs, article appraisal, article writing, and data analysis.

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Author 2 - Chung-Jen Chen - Advising the direction of study, classification of arthritis, critical appraisal of the included articles and revise the manuscript.