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.

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).

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To cite: Chen et al. New-Onset Inflammatory Arthritis After Covid-19 Vaccination. Inplasy protocol 202270128. doi: 10.37766/inplasy2022.7.0128

Received: 31 July 2022
Published: 31 July 2022

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Support: None.

Conflicts of interest: None declared.
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 \( 2\times2 \) 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 (\( p = 0.016 \), by \( 2\times2 \) 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 \( 2\times2 \) 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.