11th College of Pharmacy Research Day
يوم البحث العلمي بكلية الصيدلة

جامعة الملك سعود
King Saud University

Systematic Review and Meta-Analysis on the Safety of COVID-19 Vaccines: A Focus on Myopericarditis using Real-World Data

Renad Alnahit[1], Haifa Alnafa[1], Hadeel Alkofide[2], Basma Alfageh[2], Abdullah Almohazei[3], Khalid Alkharfy[2]

1 College of Pharmacy, King Saud University; 2 Department of Clinical Pharmacy, College of Pharmacy, King Saud University; 3 Pharmaceutical Care Division, King Faisal Specialist Hospital Specialist Hospital and research Center.

INTRODUCTION

- Vaccination is an essential component of the public health strategy to end the coronavirus disease 2019 (COVID-19) pandemic [1].
- Although COVID-19 vaccination can be associated with minor side-effects, which could be more intense after the second dose, more serious events have been reported[2].
- Emerging reports raise concern on the potential association between the COVID-19 vaccines and myopericarditis[3].
- Few observational studies have investigated the association between myopericarditis and COVID-19 vaccination, with conflicting results[4-5].
- Therefore, this study aimed to investigate the incidence of myopericarditis following COVID-19 vaccination with a focus on specific subgroups.

OBJECTIVES

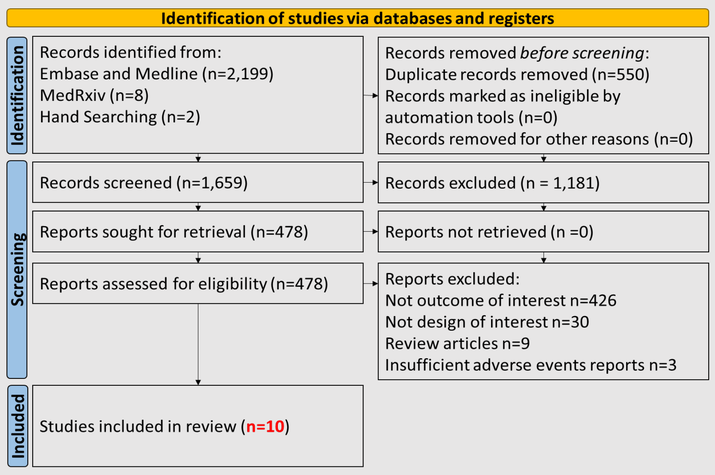
- Measure the incidence of myopericarditis post COVID-19 vaccination using real-world data.
- Examine the rate of myopericarditis following COVID-19 vaccination in specific subgroups based on gender, age, and vaccine type.

METHODS

- **Study design:** Systematic review and meta-analysis, following the PRISMA 2020 guidelines[6].
- **Eligibility criteria:** Observational studies reporting on myopericarditis following COVID-19 vaccination using any type of vaccine at any dose were included. Case reports and case series were excluded.
- **Data sources:** A Systematic search of Medline, Embase, and MedRxiv using keywords e.g., mRNA vaccines and myocarditis for studies published between December 2019-March 2022. In addition to, hand searching of eligible studies.
- **Study selection:** Screening was performed by two researchers independently. Titles and abstracts of the searched studies were screened and articles deemed eligible were retrieved for full-text screening.
- **Data extraction:** Two reviewers independently extracted information on study design, vaccination details, number of vaccinated subjects, and myopericarditis cases. Data stratified by gender, age, and vaccine type were extracted when available.
- **Quality assessment:** Evaluation of the risk of bias was performed using Newcastle Ottawa scale by two researchers independently.
- **Data analysis:** Random effect models were used when pooling crude numbers using R statistical software.

RESULTS

Figure 1. PRISMA Flow Diagram



- Quality assessment: studies ranged between medium to high quality.

RESULTS

Figure 2. Incidence of myopericarditis post COVID-19 vaccination

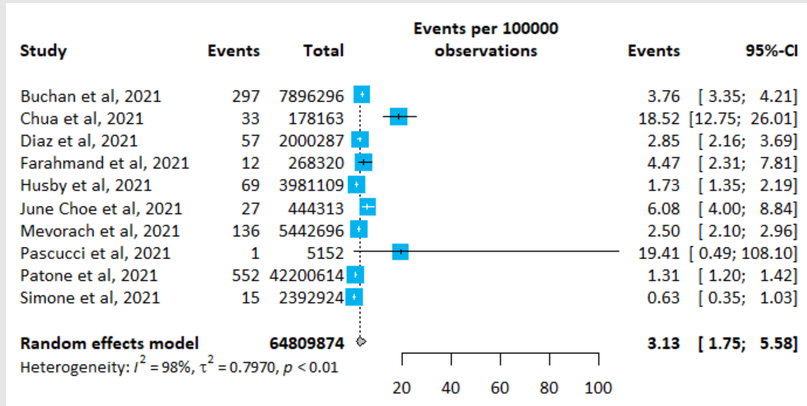


Figure 3. Myopericarditis post vaccination: males vs. females

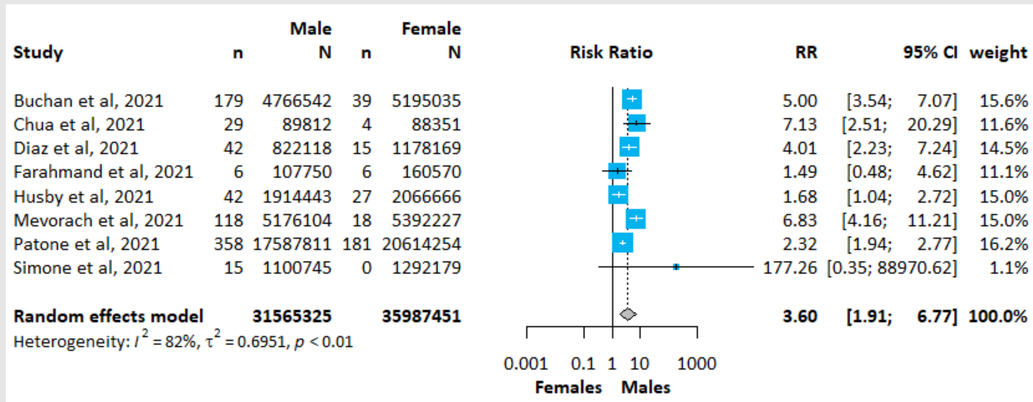


Figure 4. Myopericarditis post vaccination: mRNA-1273 vs. BNT162b2 vaccines

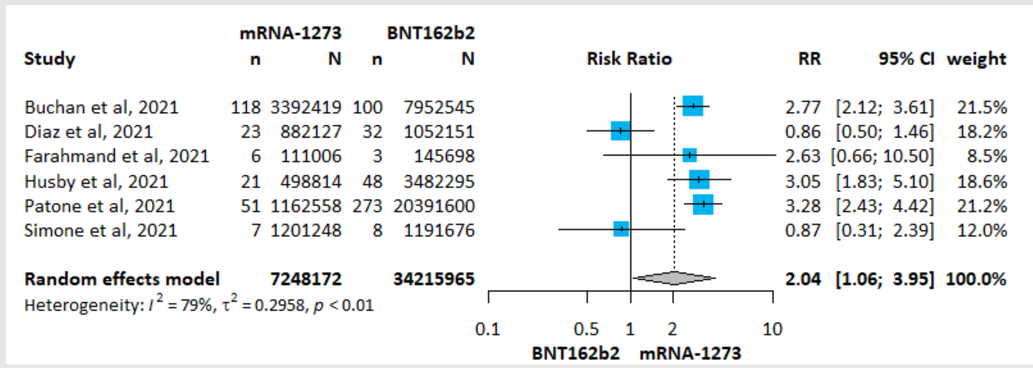
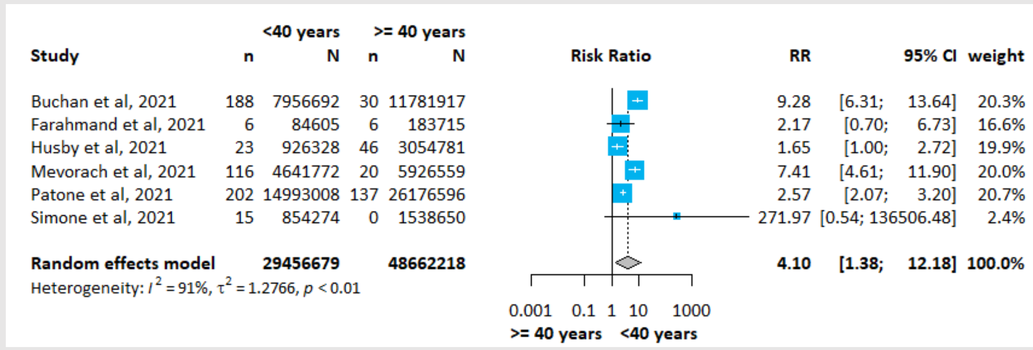


Figure 5. Myopericarditis post vaccination: < than 40 vs. ≥ than 40 years



DISCUSSION & CONCLUSION

This study indicates that myopericarditis rate following COVID-19 vaccination is very low (<0.001). However, this risk seems to be somewhat higher in certain subgroups.

The high heterogeneity in the meta-analysis, and the low number of studies included in specific subgroups limits the strength of the evidence presented here.

Additional studies and long-term population-level surveillance are strongly needed to determine the rate of myopericarditis in certain subgroups.

REFERENCES

1. Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 Vaccination Program. JAMA. 2020;323(24):2458-2459. doi:10.1001/jama.2020.8711
2. Pormohammad A, Zarei M, Ghorbani S, et al. Efficacy and Safety of COVID-19 Vaccines: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. *Vaccines* (Basel). 2021;9(5):467.
3. Albert E, Aurigemma G, Saucedo J, Gerson DS. Myocarditis following COVID-19 vaccination. Radiol Case Rep. 2021;16(8):2142-2145.
4. Husby A, Hansen JV, Fosbøl E, et al. SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. *BMJ*. 2021;375:e068665.
5. Mevorach D, Anis E, Cedar N, et al. Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel. N Engl J Med. 2021;385(23):2140-2149.
6. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.