Clinical outcomes within 12 months after myocarditis or pericarditis with and without recent COVID-19 vaccination: a multi-country VAC4EU European cohort

L.C. Zwiers[1,2], F.M.A. van der Velden[1], S. St Laurent[3], D.B. Esposito[3], L. Zhu[3], V.V. Urdaneta[3], D. Weibel[4], A. Lupattelli[5], A.A. Desalegn[5], M. Zidan[5], V. Ehrenstein[6], J. Wheler[6], F. Villalobos[7], C.A. Bissacco[7], D. Morris[8,9], C.M. Fry[8,9], A. Urchueguía-Fornes[10,11], J.J. Carreras Martínez[10,11], D.E. Grobbee[1,2], **D.S.Y. Ong**[1,2,12]

[1]Julius Clinical; [2]Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht; [3]Moderna, Inc.; [4]Vaccine Monitoring Collaboration for Europe (VAC4EU); [5]Pharmacoepidemiology and Drug Safety Group, Department of Pharmacy, University of Oslo; [6]Aarhus University and Aarhus University Hospital; [7]Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina; [8]Drug Safety Research Unit; [9]University of Portsmouth; [10]FISABIO – Public health; [11]CIBER-ESP, Instituto de Salud Carlos III, Madrid; [12]Franciscus Gasthuis & Vlietland

Disclosures: LZ, FvdV, DG, DO work or have previously worked (part-time) for Julius Clinical Ltd., which is an Academic Contract Research Organization that receives financial support from Moderna TX, Inc. to conduct research on the cardiovascular safety of COVID-19 vaccination. SS, DE, and VU-are employees of ModernaTX, Inc.; LZ is a former employee. All hold stock/stock options in the company. DW is working for VAC4EU and University medical Center Utrecht (NL) and PI of the Pfizer COVID-19 Vaccine PASS study. Aarhus University was subcontracted by Julius Clinical to provide selected services for this study. VE and JW are salaried employees of Aarhus University. AUF and MHS are working on other projects, not related to this study, funded by pharmaceutical companies; DM and CF are employed by the DSRU, an independent charity (No 327206) and non-profit organisation associated with the University of Portsmouth. The DSRU conducts projects funded by public and private organisations, including pharmaceutical companies. This study, protocol number 23_003471, is based in part on data from the Clinical Practice Research Datalink obtained under license from the UK Medicines and Healthcare Products Regulatory Agency. The data is provided by patients and collected by the NHS as part of their care and support.

BACKGROUND

- Myocarditis and pericarditis are rare events reported after COVID-19 mRNA vaccination, including mRNA-1273.
- Long-term follow-up of adjudicated cases is needed to better understand clinical course and longer-term outcomes.

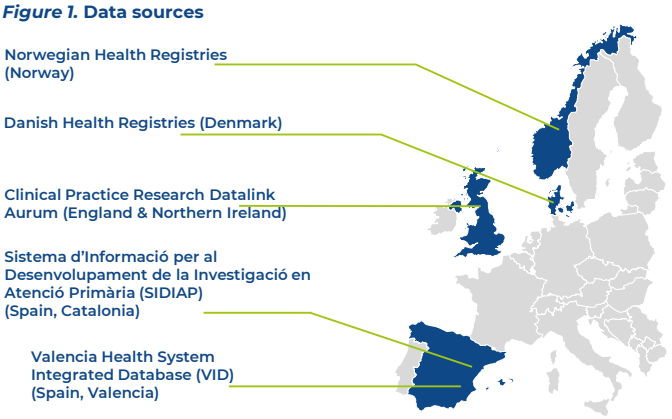
OBJECTIVES

To describe outcomes among adjudicated myocarditis and pericarditis cases with and without recent COVID-19 vaccination

METHODS

Data:
Secondary healthcare data from five VAC4EU network data expert and access partners (DEAPs) across 4 European countries (Figure 1) were used. All analyses were performed separately per data source and results are presented accordingly.

Figure 1. **Data sources**



Study period:
January 2021– August 2024 (varying by source)

Cohort inclusion:

- Diagnosis code for myocarditis or pericarditis, with symptom onset within 30 days after mRNA-1273 vaccination (exposed), or without any recent COVID-19 vaccination (unexposed)
- ≥ 1 year enrollment in database before myo-/pericarditis onset
- Met criteria for definitive, probable, or possible case according to Brighton Collaboration Case Definition

Case adjudication:
Performed for all exposed and a 1:1 matched age- and sex-sample of unexposed cases. Medical records were reviewed by local clinicians.

Outcomes:
Assessed at 30 days, 90 days, 6 months and 12 months after myocarditis or pericarditis onset:

- Cardiac events
- Thromboembolic events
- All-cause hospital readmission for inpatient stay
- Severe outcomes (hospital readmission, ICU admission, or death)
- Death

Outcomes were defined as ≥1 event per period and are presented as percentages; analyses were descriptive only.

RESULTS

- 463 – 2,146 myocarditis and 1,538 – 4,990 pericarditis cases per data source identified based on diagnosis codes
- 19-85 myocarditis/pericarditis cases included in analyses after sampling of cases and performing adjudication (Table 1)
- Median age of adjudicated cases varied widely across data sources
- Prior comorbidities were present in both exposed and unexposed cases

Among exposed myocarditis cases:

- No cases were observed among several thrombotic, cardiovascular, or cerebrovascular events at 1, 3, or 6 months in any country, including thrombocytopenia, acute cardiovascular injury, haemorrhagic stroke, ischemic cerebral attack, myocardial infarction, cardiomyopathy, and cardiogenic shock
- No sudden cardiac deaths were observed across follow-up periods
- Hospital readmission rates were the same or lower than for unexposed cases across follow-up periods
- A shorter median hospital stay was observed comparing exposed to unexposed cases (Table 2)

Patterns were similar for exposed pericarditis cases

Table 1. **Number myocarditis and pericarditis cases included in the analytical cohorts and characteristics of cases**

		Myocarditis		Pericarditis	
	Data source	**Exposed**	**Unexposed**	**Exposed**	**Unexposed**
Number of adjudicated cases	Danish registries	0*	0*	0*	0*
	Norwegian registries	28	30	39	46
	CPRD Aurum	11	8	12	11
	SIDIAP	24	18	23	22
	VID	29	38	24	28
Median age	Danish registries	32.7	31.0	31.7	36.2
	Norwegian registries	27.2	25.7	39.9	39.7
	CPRD Aurum	61.2	55.3	59.3	65.3
	SIDIAP	37.0	29.5	43.6	45.5
	VID	36.6	38.0	54.0	52.2
Number of cases with prior comorbidity[#]	Danish registries	0*	10*	0*	10*
	Norwegian registries	<5	10	12	19
	CPRD Aurum	5	5	7	8
	SIDIAP	11	5	6	12
	VID	16	15	19	18

*Total numbers for Danish registries were rounded to nearest 100 or nearest 10; [#]Prior comorbidity is defined as a record of any comorbidity of interest in 2 years before myo-/pericarditis diagnosis

Table 2. **Mean length of hospital stay of exposed and unexposed cases among cases that had at least one inpatient admission**

Myocarditis		**N exposed, N unexposed**	**Exposed cases**	**Unexposed cases**
Mean number of days in the hospital (SD)	Danish registries	30, 40	3.3 (4.1)	4.2 (5.1)
	Norwegian registries	28, 22	4.3 (1.9)	8.3 (6.8)
	CPRD Aurum	NA	NA	NA
	SIDIAP	15, 11	13.2 (14.9)	34.3 (63.7)
	VID	22, 27	6.4 (6.1)	8.6 (5.6)
Pericarditis				
Mean number of days in the hospital (SD)	Danish registries	10, 20	3.2 (2.7)	4.6 (4.8)
	Norwegian registries	28, 41	3.6 (2.9)	4.7 (4.7)
	CPRD Aurum	NA	NA	NA
	SIDIAP	15, 17	14.0 (14.5)	19.6 (25.6)
	VID	16, 24	8.2 (5.1)	11.0 (14.4)

N exposed/unexposed indicates the number of individuals with at least an admission per group; NA: Not Available; Numbers for CPRD Aurum are not reported due to very small case counts; for SIDIAP, average length of hospital stay was influenced by outliers

CONCLUSIONS

- Across 5 European data sources and multiple follow-up periods, adjudicated myocarditis or pericarditis cases exposed to mRNA-1273 vaccination showed no cases of several thrombotic, cardiovascular, or cerebrovascular outcomes
- Findings for these clinically confirmed cases were consistent across databases

Presented at ESCMID Global 2026, April 17-21, Munich, Germany

Contact
David Ong, MD, PhD, PharmD
davidsyong@gmail.com