

Myocarditis Outcomes Following mRNA COVID-19 Vaccination

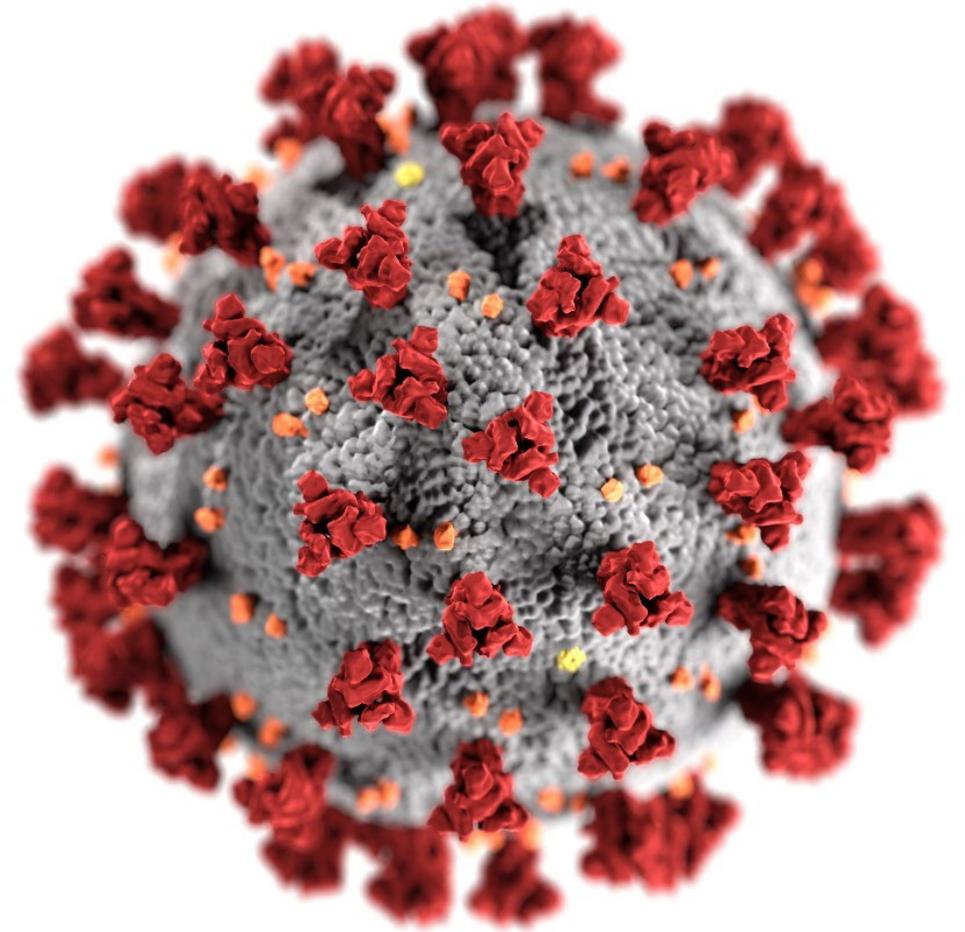
Preliminary Data: data are subject to change

**Advisory Committee on Immunization Practices
February 4, 2022**

Ian Kracalik PhD MPH

Vaccine Safety Team

CDC COVID-19 Vaccine Task Force



cdc.gov/coronavirus

Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC)
- Mention of a product or company name is for identification purposes only does not constitute endorsement by CDC or FDA



Myocarditis following mRNA COVID-19 vaccination

- Evidence from safety monitoring systems in multiple countries supports the finding of an increased, but still rare, risk of myocarditis following mRNA COVID-19 vaccination*
 - Risk:
 - Highest in adolescents and young adults
 - Males > females
 - Following dose 2 > dose 1
 - Onset within a few days of vaccination, mostly within a week
 - Severity of cases varies; most who presented to medical care have responded well to medications and rest
 - Assessment of myocarditis health effects after COVID-19 vaccination in progress* <https://www.who.int/news/item/09-07-2021-gacvs-guidance-myocarditis-pericarditis-covid-19-mrna-vaccines>



CDC enhanced surveillance for myocarditis outcomes after mRNA COVID-19 vaccination in Vaccine Adverse Event Reporting System (VAERS) case reports*

- Purpose: Assess functional status and clinical outcomes among individuals reported to have developed myocarditis after mRNA COVID-19 vaccination
- Methods: A two-component survey conducted at least 90 days after the onset of myocarditis symptoms
 - Patient survey: Focused on 12–29 years of age, ascertain functional status, clinical symptoms, quality of life, and need for medication or other medical treatment
 - Healthcare provider (e.g., cardiologist): Gather data on cardiac health and functional status
- Timeline: Data collection August 2021–January 2022



* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myo-outcomes.html>

Preliminary data from surveys of patients at least 90 days post myocarditis diagnosis



Outreach focusing on myocarditis patients 12–29 years of age

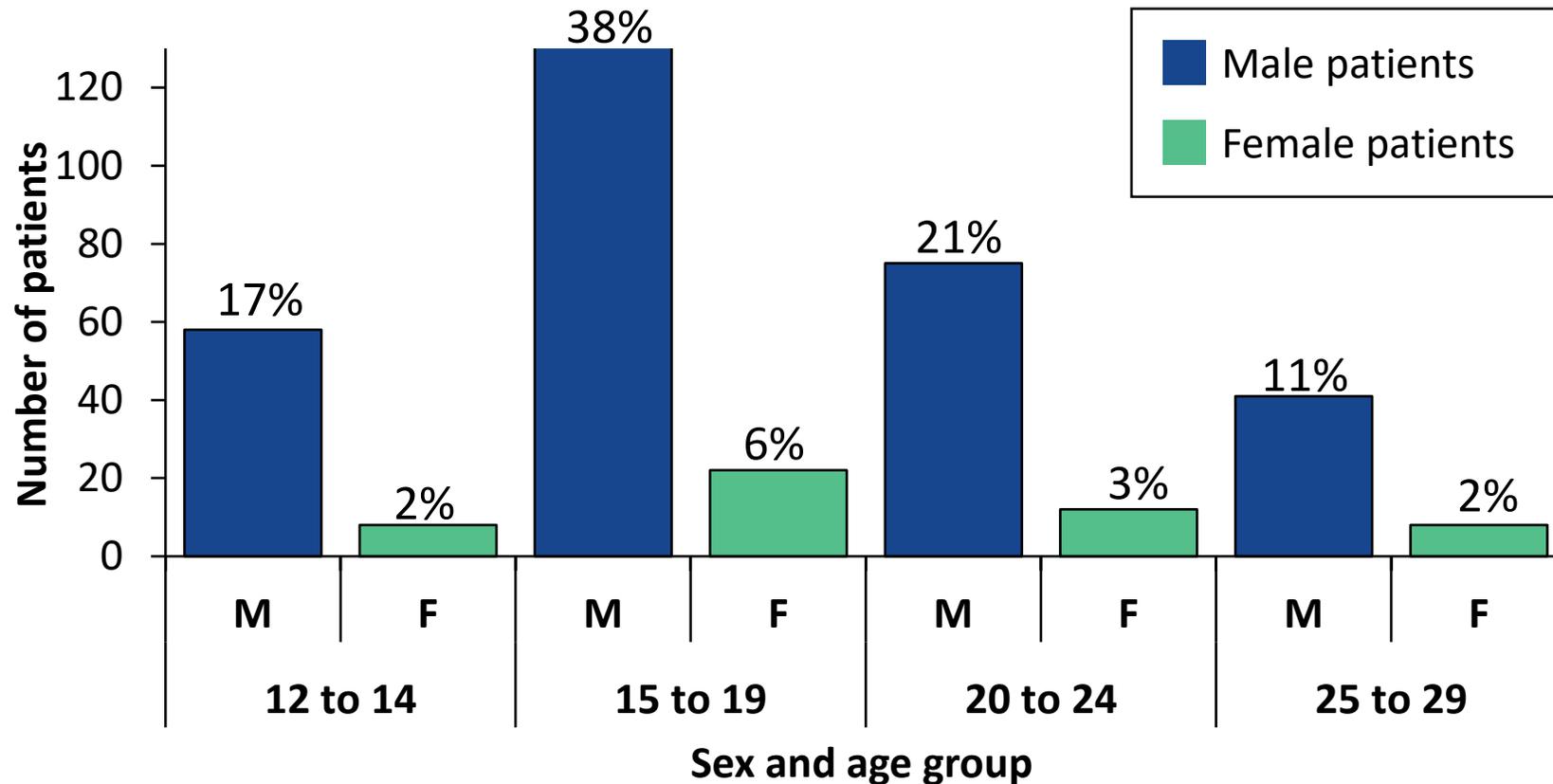
- As of November 2021, VAERS had received ~989 reports of myocarditis or myopericarditis after COVID-19 vaccination that met CDC case definition*
- Of these, ~850 patient ages 12–29 years had reached 90 days post-myocarditis diagnosis
 - Of ~850 patients 90 days post diagnosis, 648 (81%) had a phone number listed
 - Of the ~648 patients who were called, ~360 (56%) completed the survey; ~270 (42%) were unreachable and 18 (3%) declined to participate
 - For the 360 patients interviewed, time from myocarditis onset to interview was 143 days (IQR: 131, 162)

* <https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm>

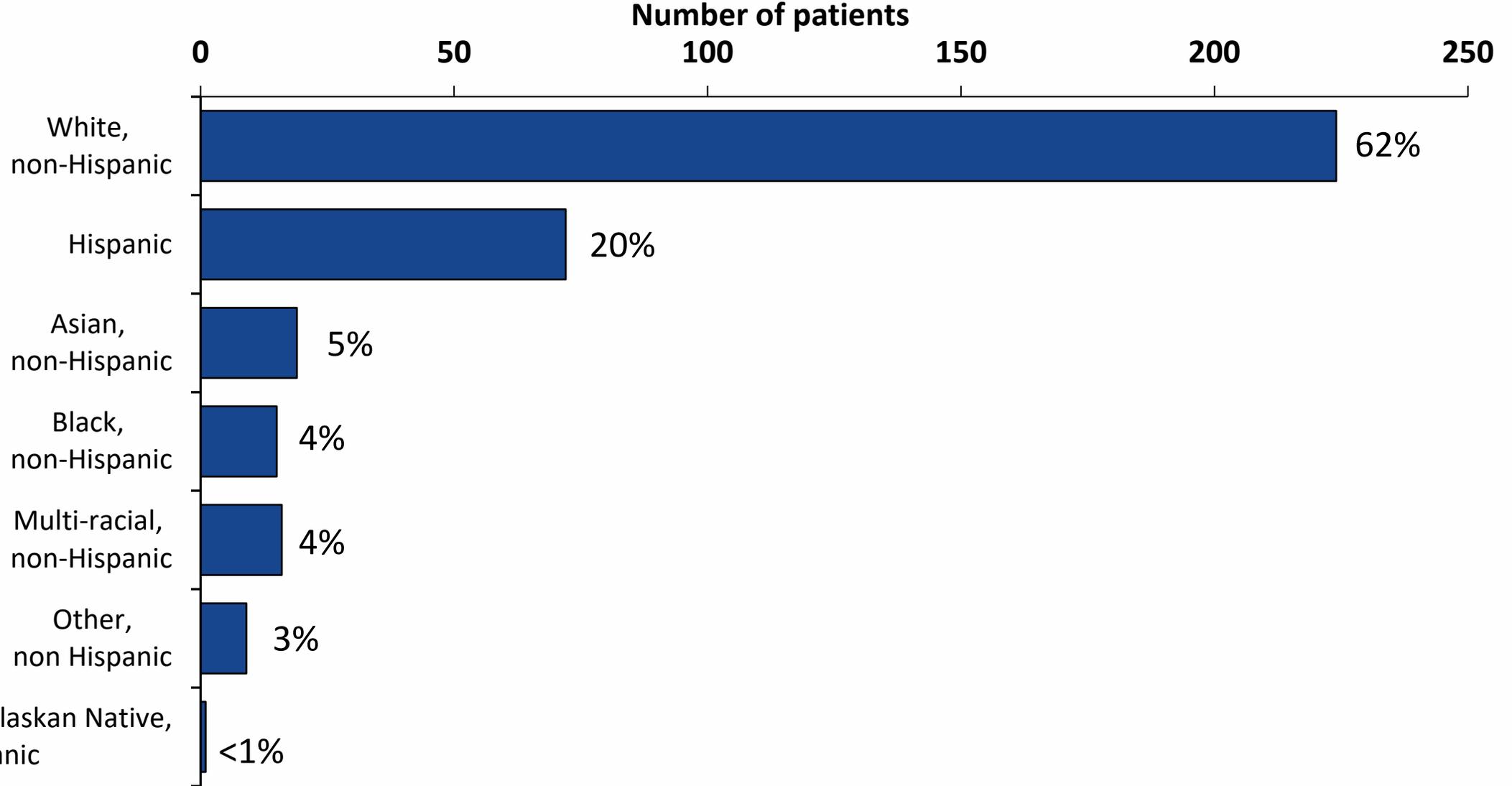


Most patients diagnosed with myocarditis were young males

- Median patient age was 18 years (IQR: 15–22);
- Of the 360 patients 90 days post myocarditis diagnosis, 86% (308) were male



Race and ethnicity of myocarditis patients (N=360)



American Indian or Alaskan Native, non-Hispanic



*4 patients did not provide a response

Prior to their myocarditis diagnosis, most patients received two doses of a COVID-19 vaccine

- **87% (314/360)** received two doses of a COVID-19 vaccine
 - Of those who received two doses, **98% (307/314)** reported receiving both doses before they were diagnosed with myocarditis
 - **9% (31/360)** had a positive COVID-19 test before their myocarditis diagnosis

Self reported previous medical history among patients with myocarditis after mRNA COVID-19 vaccination (N=360)

- **60 (17%)** had any condition
 - **11 (3%)** had an arrhythmia
 - **6 (2%)** had congenital heart disease
 - **6 (2%)** had a history of myocarditis
 - **2 (<1%)** had Kawasaki disease
 - **1 (<1%)** had previous heart failure
 - **32 (9%)** had a history of asthma
 - **7 (2%)** had an autoimmune disorder
 - **5 (1%)** genetic or chromosomal condition
 - **4 (1%)** were immunosuppressed
 - **1 (<1%)** had a history of Leukemia
 - **1 (<1%)** had type 1 diabetes



Most patients with myocarditis after vaccination reported being hospitalized at the time of myocarditis diagnosis (n=360)

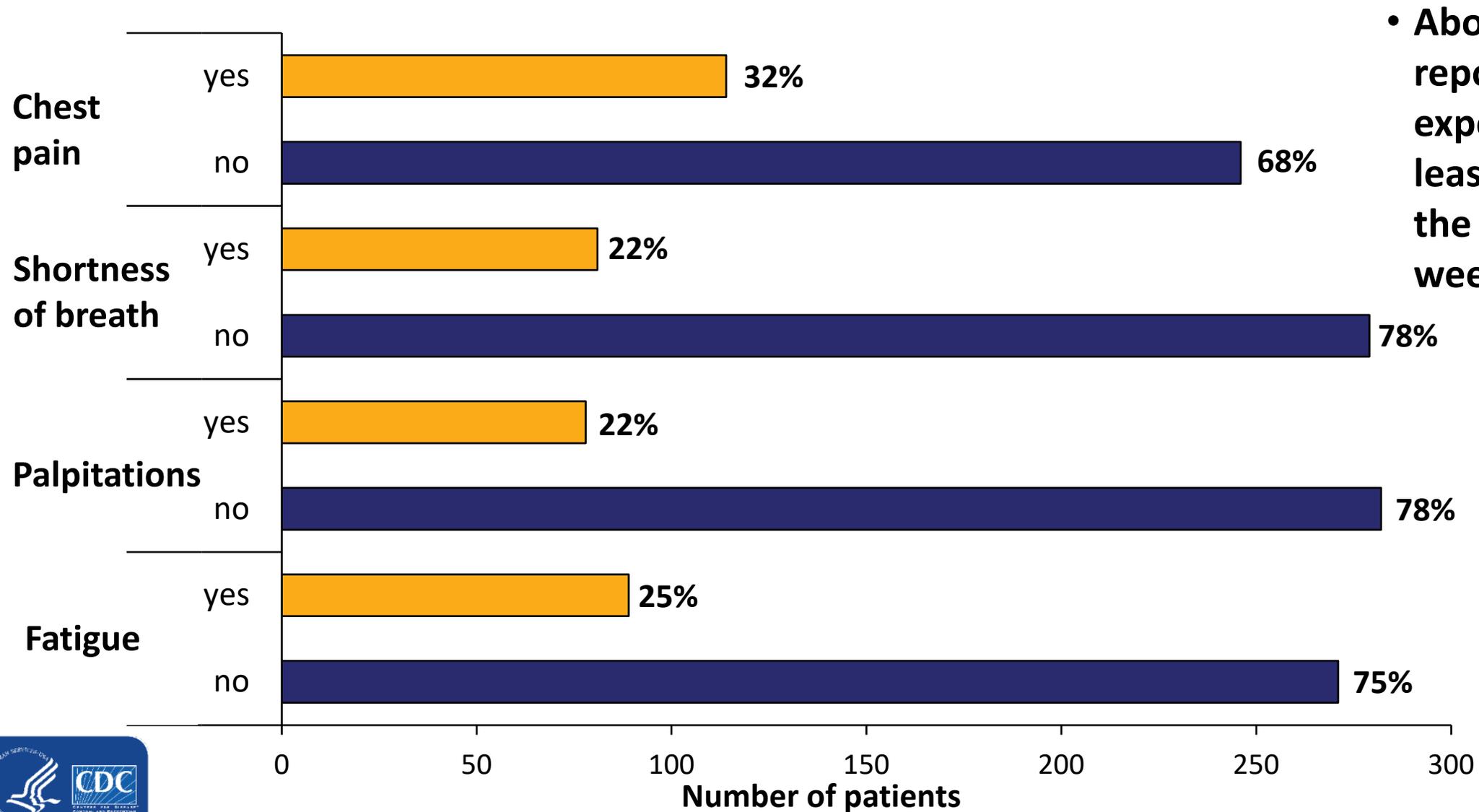
- **92% (324)** were hospitalized
 - **4% (13)** were readmitted following myocarditis; **8 of 13 (62%)** were readmitted because of a concern with the heart
 - **20% (71)** were prescribed medication for their heart as of their last appointment with the provider



Missed school or work within the 2 weeks prior to the date of the interview reported among patients with myocarditis after vaccination (N=360)

- **46 (8%)** reported missing school
 - Of these, **10 (37%)** believed it was due to their myocarditis
- **19 (5%)** missed work
 - Of these, **7 (37%)** believed it was due to their myocarditis

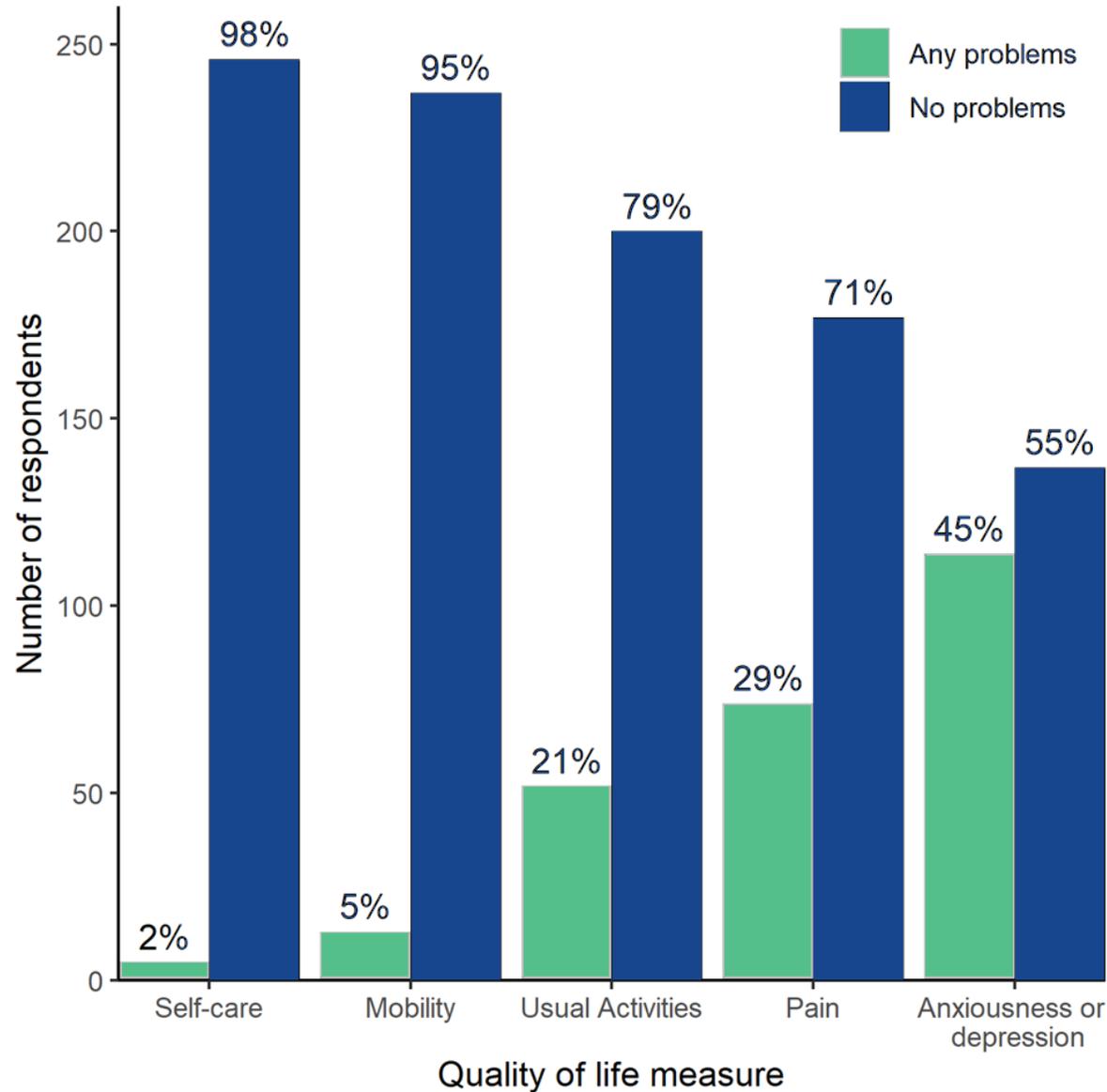
Self-reported symptoms within 2 weeks prior to the date of the interview among myocarditis patients (n=360)



- About half (49%) reported experiencing at least 1 symptom in the prior two weeks



EuroQol-5D-5L measurement of health status among patients who developed myocarditis after vaccination (n=242)



Preliminary data from completed cardiologist or other healthcare provider surveys



Outreach to cardiologists or other healthcare providers

- Of the 360/648 patients interviewed, ~346 (96%) listed contact information for a cardiologist or other healthcare provider
 - Of the 346 providers with contact information listed, 229 completed a survey
 - An additional 151 providers completed surveys they had submitted for multiple patients in VAERS or provided contact information via the VAERS report
 - We were unable to contact 268 providers
 - In total, 380 providers completed the survey with a median of 191 days (IQR: 170, 216) from patient myocarditis onset to date of provider survey



The proportion of myocarditis patients cleared for physical activity by their cardiologist or healthcare provider has increased (n=380)

At time of myocarditis diagnosis, 83% of patients had restrictions on their physical activity



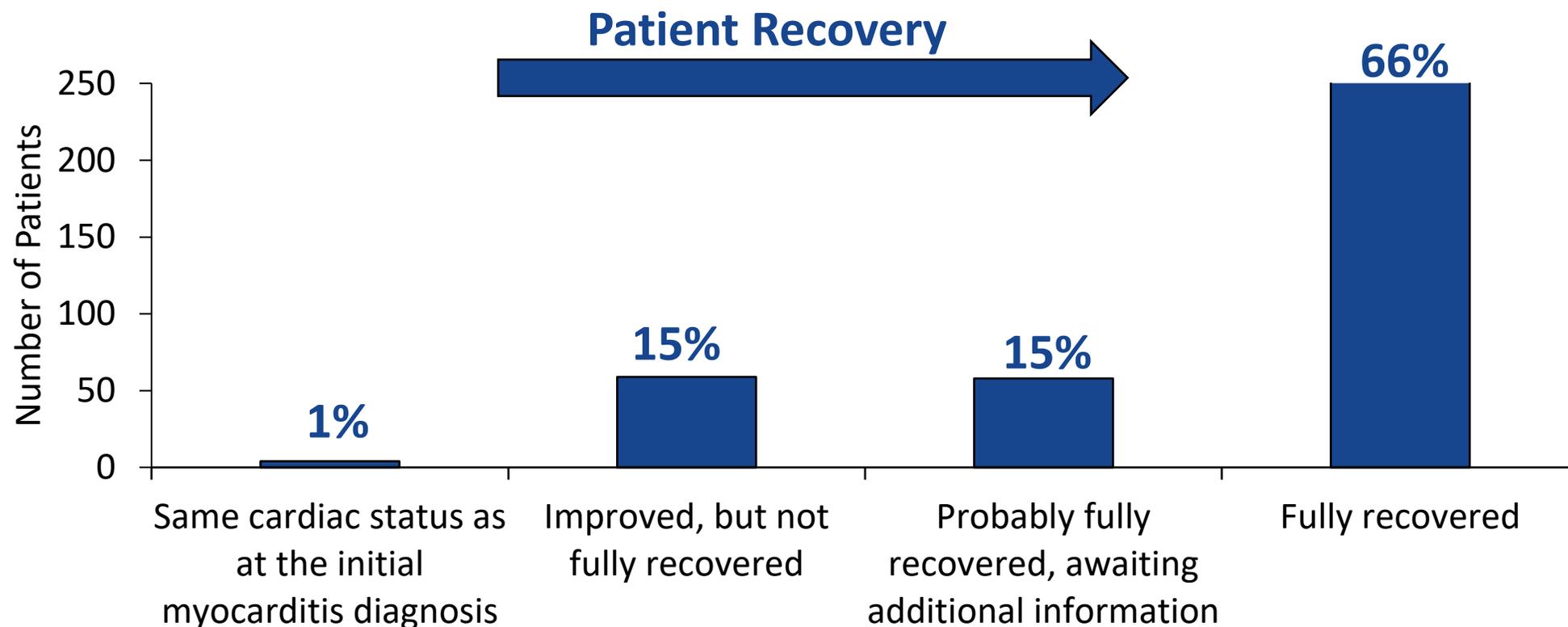
At time of provider survey, at least 90 days post diagnosis, only 39% had restrictions



*25 (7%) were unsure

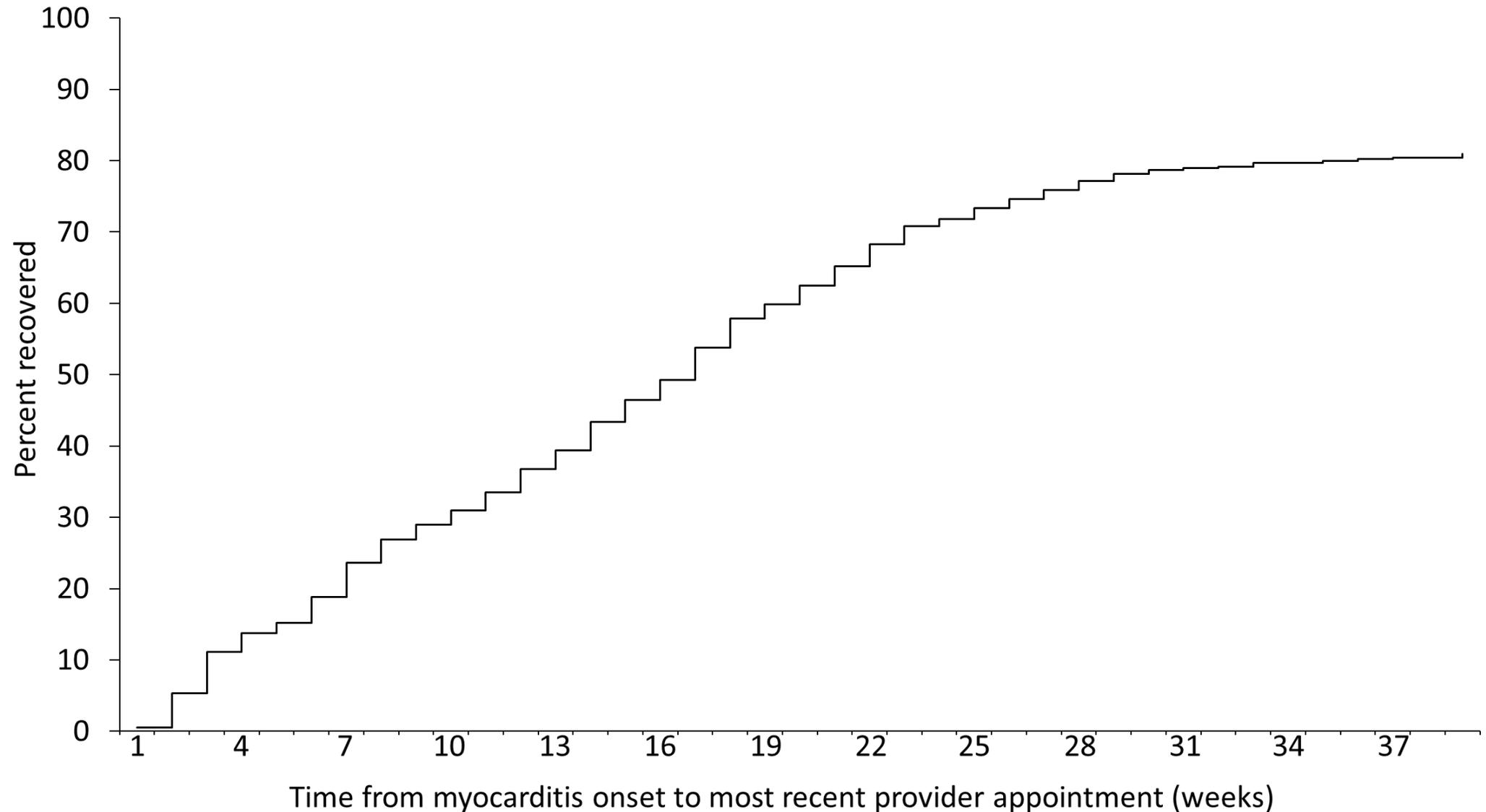
Based on the cardiologists/healthcare provider assessment, most patients appear to have fully or probably recovered from their myocarditis (n=380)

- 81% (309) of cardiologists or healthcare providers indicated the patient was fully or probably recovered

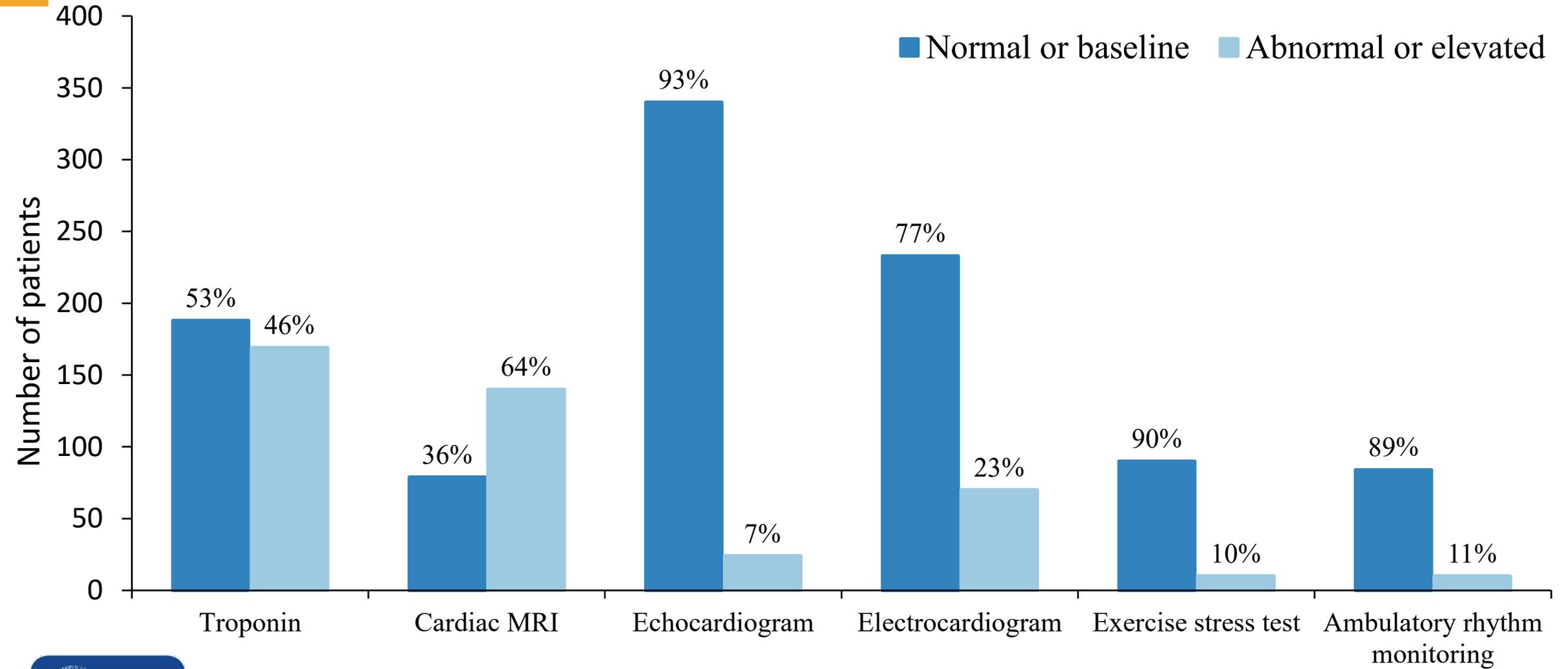


*8 providers were unsure

Proportion of myocarditis patients deemed to be fully or probably recovered by their healthcare provider (n=309)



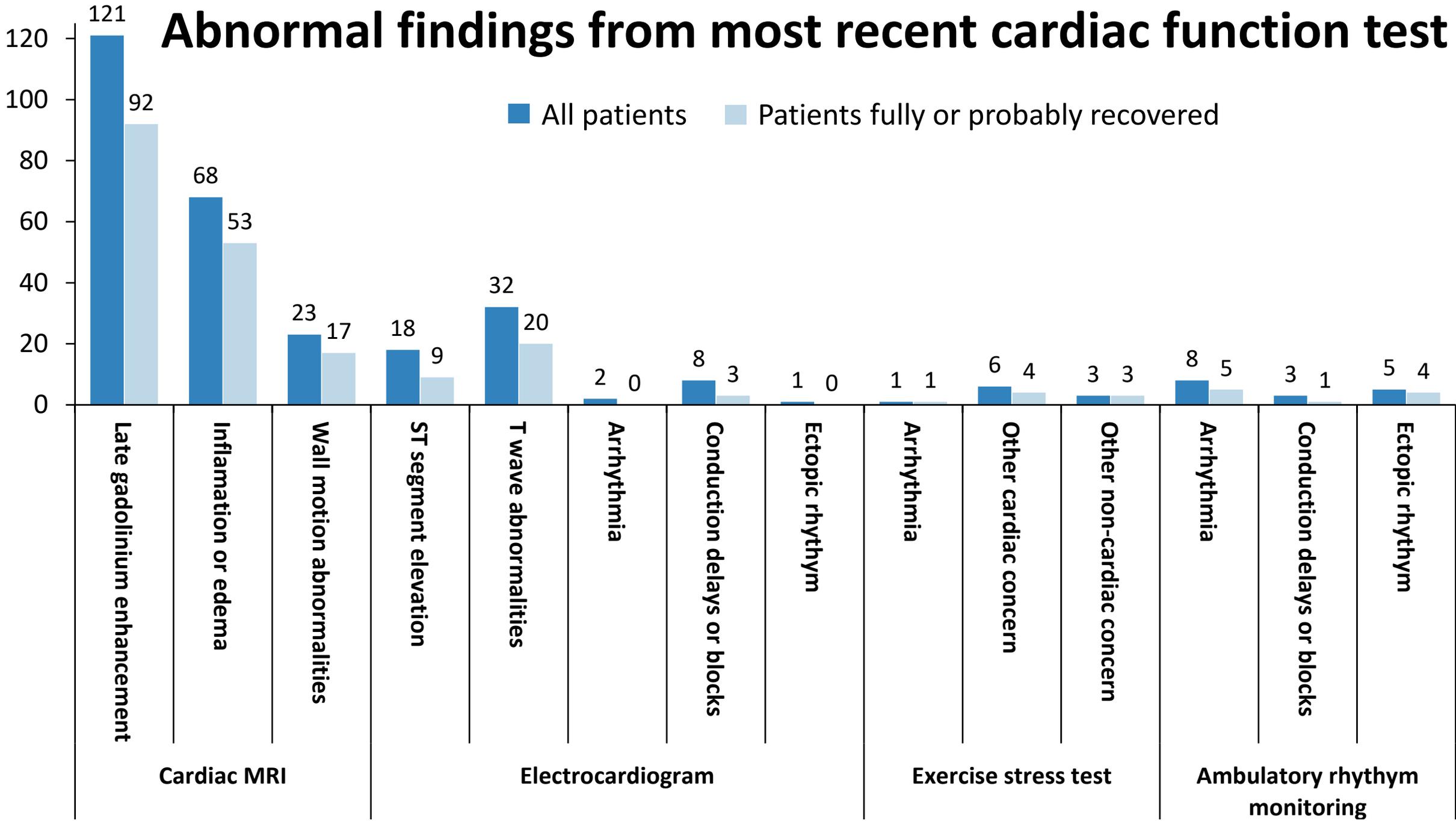
Results of the most recent cardiac function test (n=380)



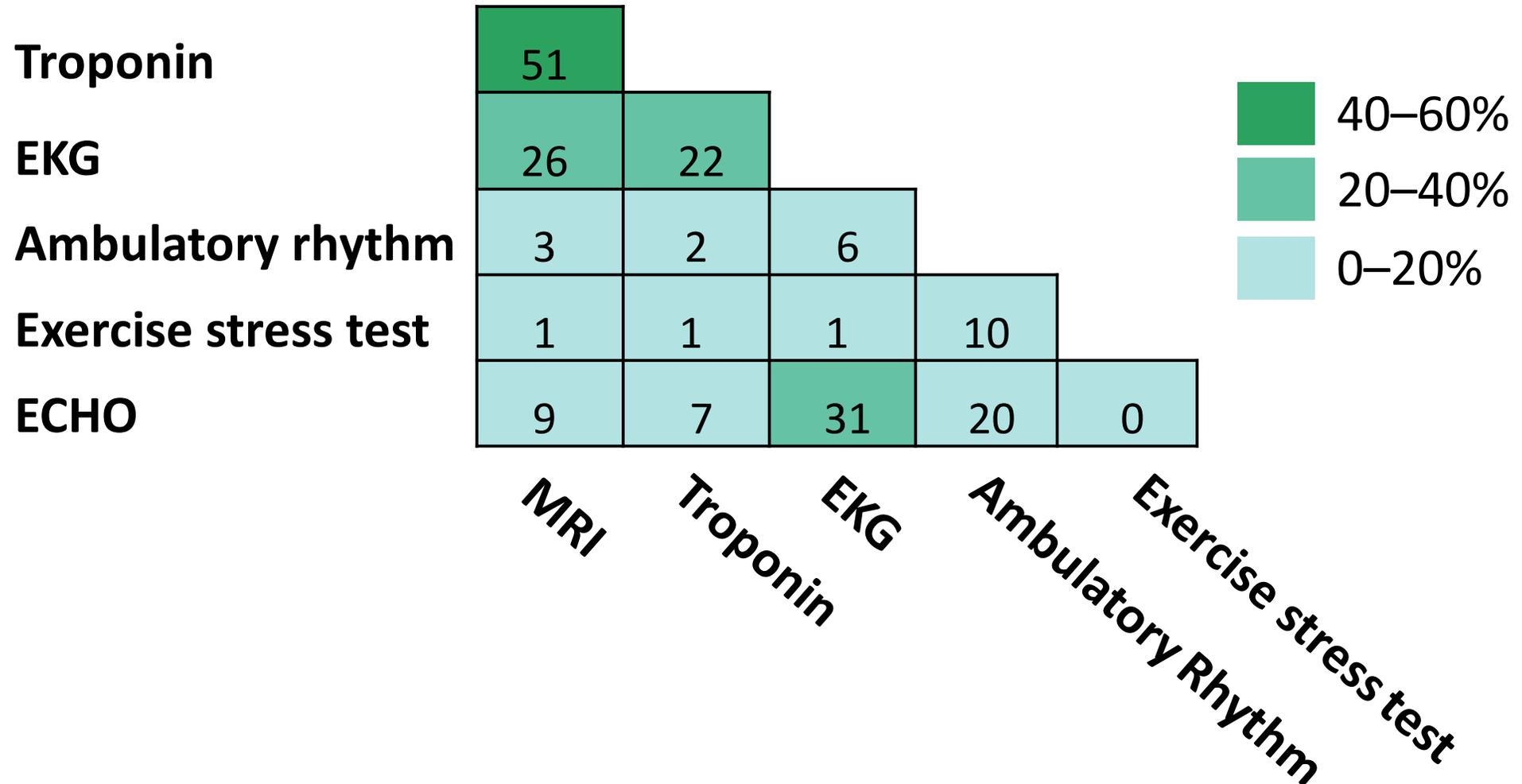
Abnormal findings from most recent cardiac function test

Number of patients

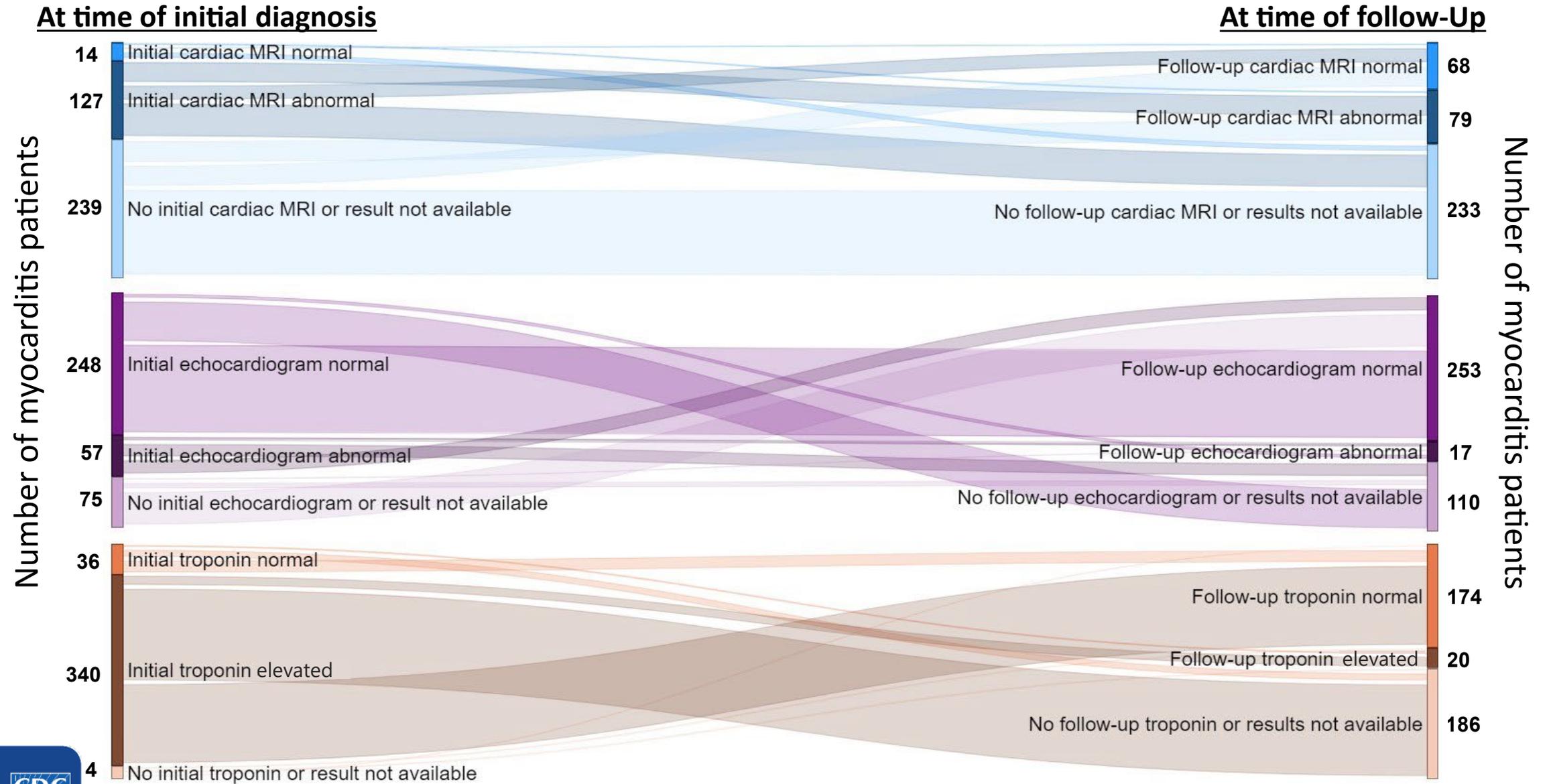
■ All patients ■ Patients fully or probably recovered



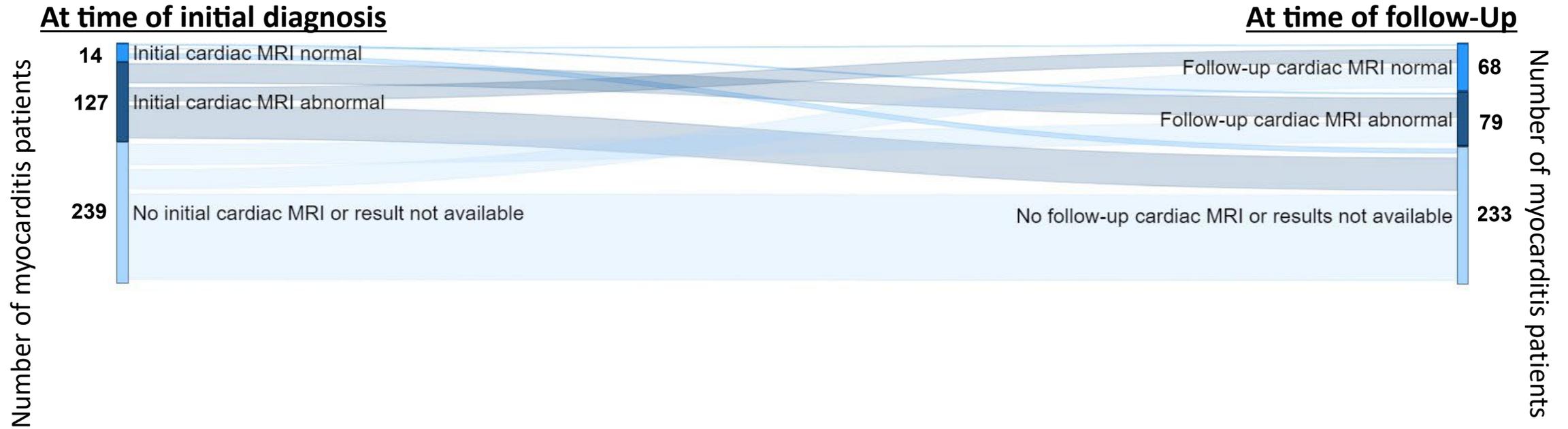
Overlap of abnormal findings among most recent cardiac function tests



Comparison of cardiac function tests at time of diagnosis and follow-up



Comparison of cardiac function tests at time of diagnosis and follow-up



Comparison of cardiac function tests at time of diagnosis and follow-up



Comparison of cardiac function tests at time of diagnosis and follow-up

At time of initial diagnosis

At time of follow-up



Cardiac assessment and symptoms among patients deemed to be recovered and not recovered from their myocarditis

Patients deemed not recovered



Patients deemed fully or probably fully recovered

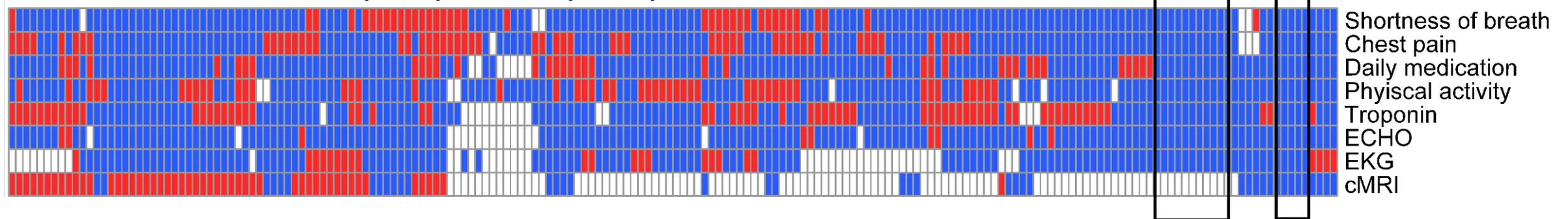


Cardiac assessment and symptoms among patients deemed to be recovered and not recovered from their myocarditis

Patients deemed not recovered

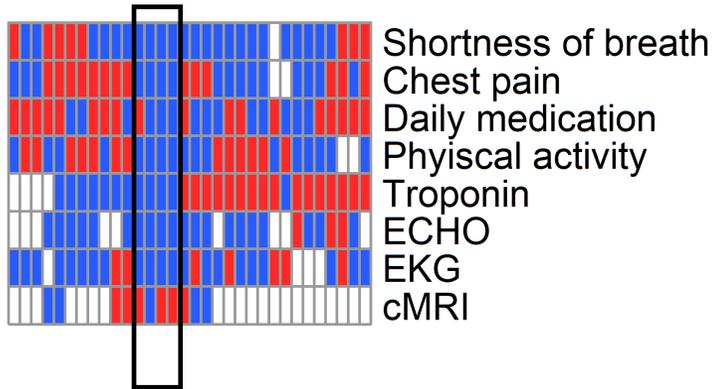


Patients deemed fully or probably fully recovered



Cardiac assessment and symptoms among patients deemed to be recovered and not recovered from their myocarditis

Patients deemed not recovered



- Normal/Baseline function or absence of symptoms
- Abnormal function or presence of symptoms
- Unknown or no test results available

Patients deemed fully or probably fully recovered



Summary

- At least 90 days after myocarditis diagnosis, most patients reported no impact on their quality of life, and most did not report missing school or work
- Only 13 (4%) were readmitted to the hospital
- Most (81%) healthcare providers indicated the patient was probably fully or fully recovered
- There did not appear to be a single test that was indicative of recovery
- To our knowledge, there were no vaccine-associated myocarditis deaths in this group
- Ongoing efforts to continue patient follow-up and contact myocarditis patients who were not yet recovered at time of survey
- Surveys are being modified for children aged 5-11 and follow-up to start in February 2022



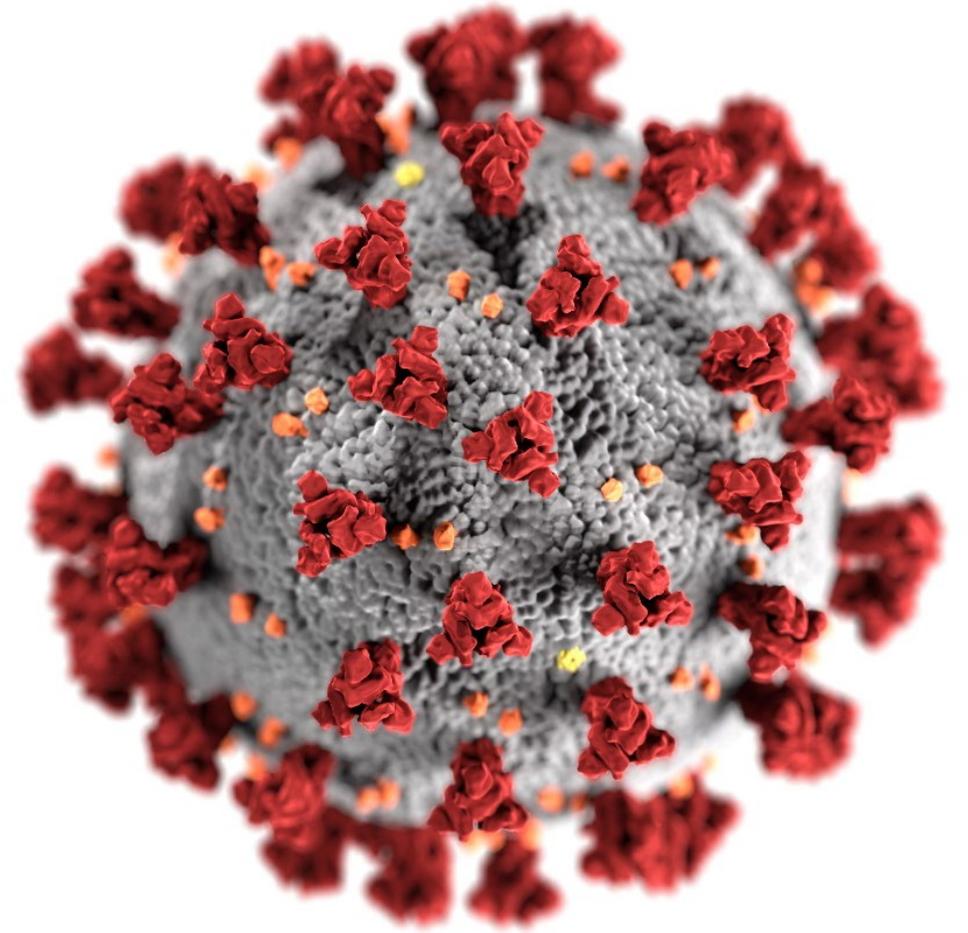
Acknowledgments

Thanks to the many people who made analysis of these data possible:

- **VAERS Team**
 - VAERS TTS abstraction team
 - VAERS Myopericarditis abstraction team
 - VAERS data team
- **Clinical Immunization Safety Assessment Project**
- **COVID-19 Vaccine Task Force Data Monitoring and Reporting Group**



Thank you!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.