Myocarditis, COVID-19 and mRNA vaccines

All you need to know to decide whether to vaccinate

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Myocarditis, COVID and mRNA vaccines

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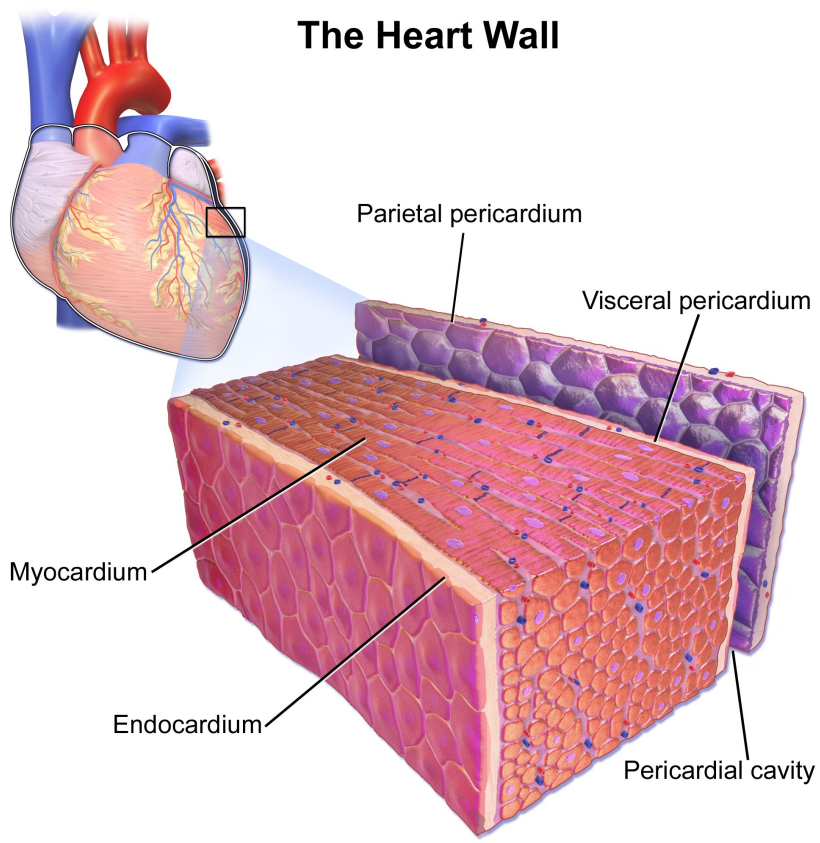
1. What is myocarditis / pericarditis?

Myocarditis is an inflammation in the heart muscle and pericarditis is an inflammation in the pericardium, a layer around the heart. They often come together, so we call this myo-pericarditis.

2. What causes myo-pericarditis?

Usually a viral infection (same virus which causes the flu or a simple cold, and now of course COVID-19). Also, other types of inflammatory diseases such as auto-immune disorders can cause myo-pericarditis.



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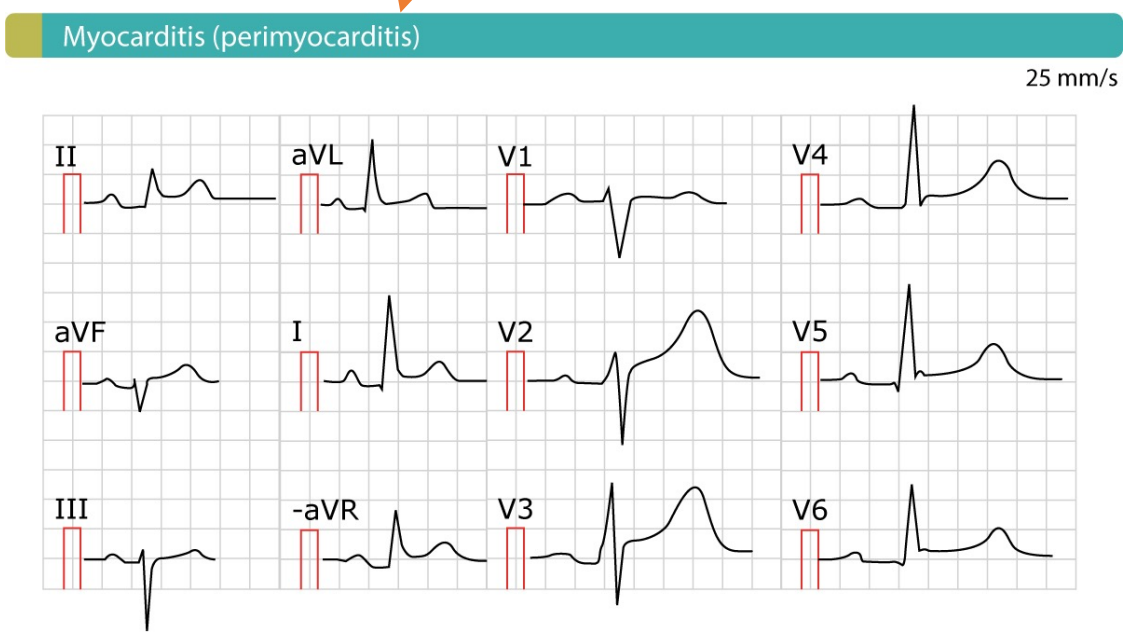
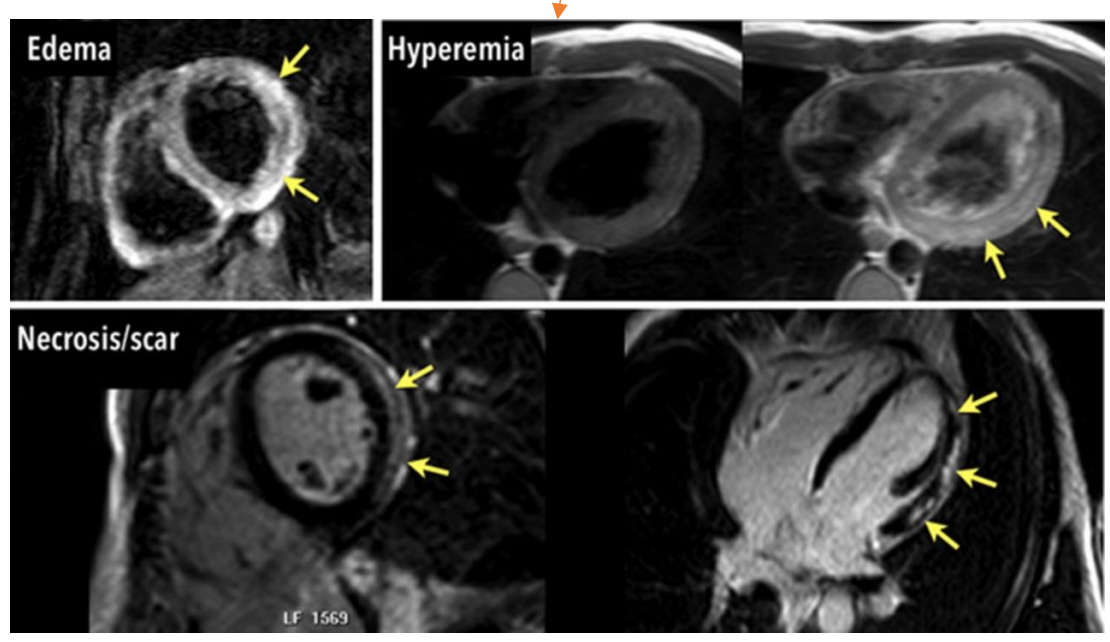
3. How to suspect someone has myo-pericarditis?

Patients present with chest pains which feels like a "knife" and the pain is typically worse on deep breathing and can radiate to the upper back. Other symptoms are shortness of breath and "flu-like" symptoms such as fever, cough, night sweats etc.

4. How do we make a diagnosis of myo-pericarditis?

We rely on the ECG and on a blood test called troponin, which shows evidence of damage to the heart muscle. More advanced tests such as cardiac MRI are often needed to document the precise location and severity of the inflammation, and also to show whether the heart function has been affected.





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5. How frequent is myo-pericarditis in the general population (before COVID)?

The table below shows the incidence of the disease per million people across age groups.

Age groups	Per million people Expected†,‡ Myocarditis/ pericarditis cases
12–15 yrs	0–1
16–17 yrs	**2–19**
18–24 yrs	**8–83**
25–39 yrs	23–228
40–49 yrs	17–166
50–64 yrs	31–314
65+ yrs	36–358
NR	—

This data is very important because it serves as a comparison to determine whether vaccination, COVID or any other disease or treatment can cause myo-pericarditis.

We can only assume that something else caused myo-pericarditis if the rates observed are higher than the numbers on this table!

Reference: Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

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6. Can COVID-19 vaccines cause myo-pericarditis?

Yes, a link has been established between mRNA vaccines and myo-pericarditis. It is more common in young males and after the second dose. Other types of vaccine do not appear to cause it.

7. How has this link been established?

Because the incidence of myo-pericarditis following mRNA vaccination was found to be higher than in the general population. Check the table below.

Age groups	Per million people **Expected†,‡** **Myocarditis/ pericarditis cases**	Per million people **Observed†** **Myocarditis/ pericarditis reports post mRNA vaccine**
12–15 yrs	0–1	2
16–17 yrs	**2–19**	**79**
18–24 yrs	**8–83**	**196**
25–39 yrs	23–228	124
40–49 yrs	17–166	51
50–64 yrs	31–314	39
65+ yrs	36–358	26
NR	—	11

Across young age groups, mRNA vaccination appears to increase the risk of myo-pericarditis.

Across older groups, this is not observed.

Reference: https://www.fda.gov/media/150054/download, slide 17

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8. How severe is vaccine-related myo-pericarditis?

The absolute vast majority of patients recover promptly with no long-term consequences, just like most myo-pericarditis caused by other viruses. There have been rare severe cases reported (3 in the US and 5 in Europe where, together, hundreds of millions of people have been vaccinated with mRNA vaccines). All patients who had severe myocarditis had comorbidities such as obesity or chronic diseases).

References:

https://www.fda.gov/media/150054/download, slide 16

https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis

Severe, life-threatening cases of myo-pericarditis following vaccination with mRNA vaccines:

8 reported cases with >350 million doses given

Incidence = less than 0.022 per million

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9. Can COVID-19 itself cause myo-pericarditis? How frequently?

Yes! Unequivocally. COVID-19, like other viruses, can cause myo-pericarditis.

It is difficult to establish precisely the incidence across all patients who develop COVID, but our best estimation is that it ranges from around ~1% in mild COVID, up to 20-50% in patients admitted to hospital with severe COVID.

Incidence of COVID-19 myo-pericarditis

~1% in mild cases
~20-50% in severe cases

References:

1. Kawakami R, Sakamoto A, Kawai K, et al. Pathological evidence for SARS-CoV-2 as a cause of myocarditis. *J Am Coll Cardiol*. 2021;77:314-325.

2. Starekova J, Bluemke DA, Bradham WS, et al. Evaluation for Myocarditis in Competitive Student Athletes Recovering From Coronavirus Disease 2019 With Cardiac Magnetic Resonance Imaging. *JAMA Cardiol.* Published online January 14, 2021. doi:10.1001/jamacardio.2020.7444

3. Tushar Kotecha, et al. Patterns of myocardial injury in recovered troponin-positive COVID-19 patients assessed by cardiovascular magnetic resonance, *European Heart Journal*, Volume 42, Issue 19, 14 May 2021, Pages 1866–1878

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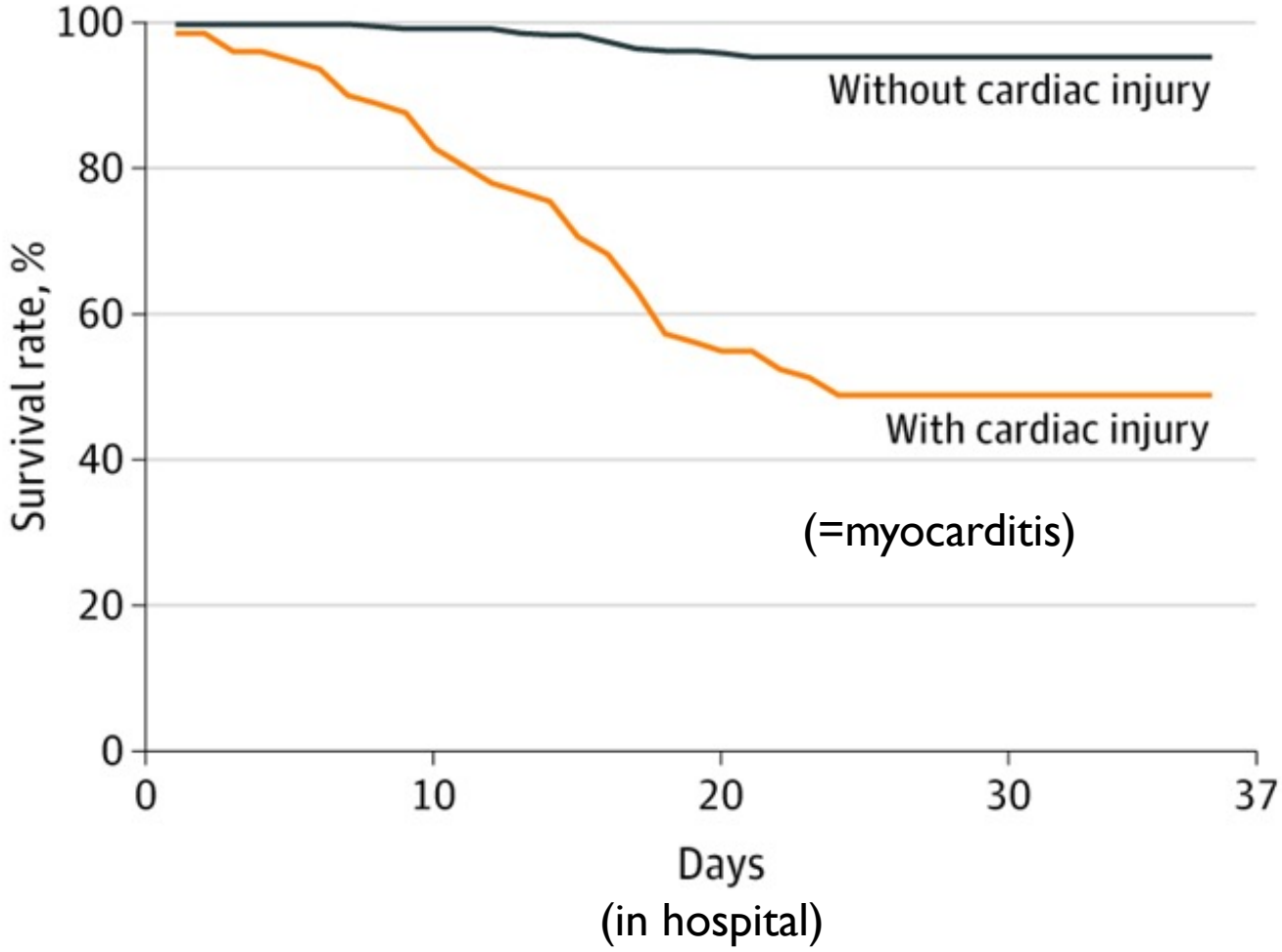
10. Is COVID myo-pericarditis life threatening?

It depends on the severity of COVID disease. In mild cases, no. It doesn't (or rarely) cause any long-term damage (just like other viruses and like the vaccine).

However,…

In severe COVID-19, myo-pericarditis is a disease with an extremely poor prognosis, with a 50% chance of death.



50% chance of death in hospitalised severe COVID cases with myocarditis

References:

1. Shi S, Qin M, Shen B, et al. Association of Cardiac Injury With Mortality in Hospitalized Patients With COVID-19 in Wuhan, China. *JAMA Cardiol.* 2020;5(7)
2. Bonow RO, Fonarow GC, O'Gara PT, Yancy CW. Association of Coronavirus Disease 2019 (COVID-19) With Myocardial Injury and Mortality. *JAMA Cardiol.* 2020;5(7)

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11. Ok, but in general what is the chance of dying from COVID across all ages?

	Population	All-cause deaths*		COVID-19 deaths†		COVID-19 deaths as percentage of all-cause deaths, %
		n	per 100 000	n	per 100 000	
USA						
0–4 years	19 810 275	23 844	120·36	67	0·34	0·28%
5–14 years	41 075 169	4990	12·15	67	0·16	1·34%
UK						
0–9 years	8 052 552	3793	47·10	7	0·09	0·19%
10–19 years	7 528 144	1109	14·73	22	0·29	1·98%
Italy						
0–9 years	5 090 482	1569	30·83	8	0·16	0·51%
10–19 years	5 768 874	772	13·38	10	0·17	1·30%
Germany						
0–9 years	7 588 635	2782	36·66	9	0·12	0·32%
10–19 years	7 705 657	1249	16·21	4	0·05	0·32%
Spain						
0–9 years	4 370 858	1369	31·31	8	0·18	0·58%
10–19 years	4 883 447	532	10·89	18	0·37	3·39%
France						
0–9 years	7 755 755	2916	37·60	7	0·09	0·24%
10–19 years	8 328 988	1068	12·82	4	0·05	0·38%
South Korea						
0–9 years	4 148 654	1519	36·61	0	0·00	0
10–19 years	4 940 455	814	16·48	0	0·00	0
Total	137 047 945	48 326	35·26	231	0·17	0·48%

The sources of these data are provided in the appendix (p 2). *Includes all deaths from approximately March 1, 2020, to Feb 1, 2021. †Includes all COVID-19 deaths reported from the start of the pandemic up to Feb 3, 2021 (USA), Jan 29, 2021 (UK), Jan 20, 2021 (Italy), Feb 9, 2021 (Germany), Feb 10, 2021 (Spain), Feb 11, 2021 (France), or Feb 3, 2021 (South Korea).

Table: **Age-specific data for seven countries showing estimated all-cause deaths compared with COVID-19 deaths**

We know that the chance of dying from COVID-19 is higher in older people, and rare amongst the young. But how rare is rare? The table on the left shows the COVID-19 mortality rate per age group (per 100000 people, so to find out per million multiply the number by 10).

References: Bhopal, Sunil S et al. **Children and young people remain at low risk of COVID-19 mortality.** The Lancet Child & Adolescent Health, Volume 5, Issue 5, e12 - e13

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Conclusions

- Both **COVID-19 disease** and **mRNA vaccines** can **cause myo-pericarditis.**
- The **incidence of myo-pericarditis** in young people following **mild COVID** disease (10 thousand per million) **is 50-125 times higher** than following **mRNA vaccines** (~80-200 cases per million).
- The occurrence of **severe myo-pericarditis** (and death) is **exceedingly rare following vaccination** (less than 0.022 per million)
- The incidence of **severe myo-pericarditis in severe COVID-19** disease is approximately **20%** and carries a near **50% mortality**.
- The overall chance of **young individuals to die** from **COVID-19** disease is **very low** (0.5 – 2.9 per million) **but still 22-131 times higher** than the chance of **dying from vaccine myo-pericarditis** (<0.022 per million).

Even amongst the young, the benefits of COVID-19 mRNA vaccination far exceeds the risks of rare side effects such as myo-pericarditis

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Final message

Even amongst the young, the benefits of COVID-19 mRNA vaccination far exceeds the risks of rare side effects such as myo-pericarditis