

Significant incidence of myocarditis after 3rd dose of anti-COVID 19 messenger RNA vaccine

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- Significant incidence of myocarditis after 3rd dose of vaccine...

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Live from ESC Congress 2022

Based on the presentation by Christian Eugen Mueller (Basel, Switzerland): "*Myocardial Inflammation/Myocarditis After COVID-19 mRNA Booster Vaccination*"

The essential

- Prior to this study, there were no prospective data on post-vaccination myocardial lesions during vaccination with an mRNA vaccine. Only the most serious hospitalized myocarditis have been reported, mainly affecting men under 18 years of age.
- The actual incidence of post-vaccination myocardial lesions is 2.8% vs 0.0035% of myocarditis in retrospective studies

- Myocardial lesions affect women more contrary to what is described in previous studies.
- The possibility of repeated doses of vaccine in order to maintain effective vaccination coverage should lead to great caution regarding possible repeated myocardial lesions and their impact on possible cardiovascular complications.

Introduction

We know that there are potentially serious side effects to the COVID 19 mRNA vaccine such as myocarditis.

In retrospective data, the main cardiac complication is myocarditis, which remains rare with an incidence of 0.0035% and mainly affects young men under 18 years of age.

However, there is a selection bias because only serious cases requiring hospitalization are reported.

The true incidence of myocardial damage would therefore likely be much higher in the general population. Moreover, due to the need for repeated doses and the large number of people to be vaccinated, even this rare complication is not anecdotal.

The aim of this study was to evaluate the real incidence of myocardial lesions during vaccinations with an mRNA vaccine in COVID 19 in a prospective manner and to evaluate possible preventive and protective measures to be applied in patients presenting with these lesions. asymptomatic myocardials.

Methodology and results

This study was prospective single center with a control arm. The study population was composed of employees of the University Hospital of Basel in Switzerland, who had received a dose of the Pfizer-BioNTech or Moderna mRNA vaccine.

The **primary endpoint** was the occurrence of a myocardial lesion, defined by an increase in serum troponin above the norm, measured on D3 post-vaccination.

In case of elevation, a new assay was performed on D4 with the possibility of carrying out further cardiological explorations. In addition, patients with myocardial lesions were contraindicated to exercise until troponinemia decreased. In all cases, follow-up was continued until D30.

The **secondary endpoints** were the comparison of the total population with patients who had been admitted for chest pain without any cardiac cause being found. Matching was performed on age, sex and history of coronary artery disease and peripheral atherosclerotic disease.

The **second secondary endpoint** was the occurrence of MACE at 30 days (death of cardiovascular origin, hospitalization for heart failure, ventricular arrhythmia and myocardial infarction).

A total of 835 patients were included, including 777 who received troponinemia assay on D3, among these patients 40 had increased troponinemia. In 18 of them, causes other than the vaccine were identified that could explain the elevated troponinemia, and in the remaining 22 no cause other than the vaccine was implicated. The population studied was mainly composed of women (69%), the average age was 37 years and the patients overwhelmingly received their 3rd^{dose} (92%). Less than 2% of them had a cardiovascular history.

The results of the study found that 2.8% of the vaccinated population had myocardial lesions, 3.7% in women and 0.8% in men (Figure 1).

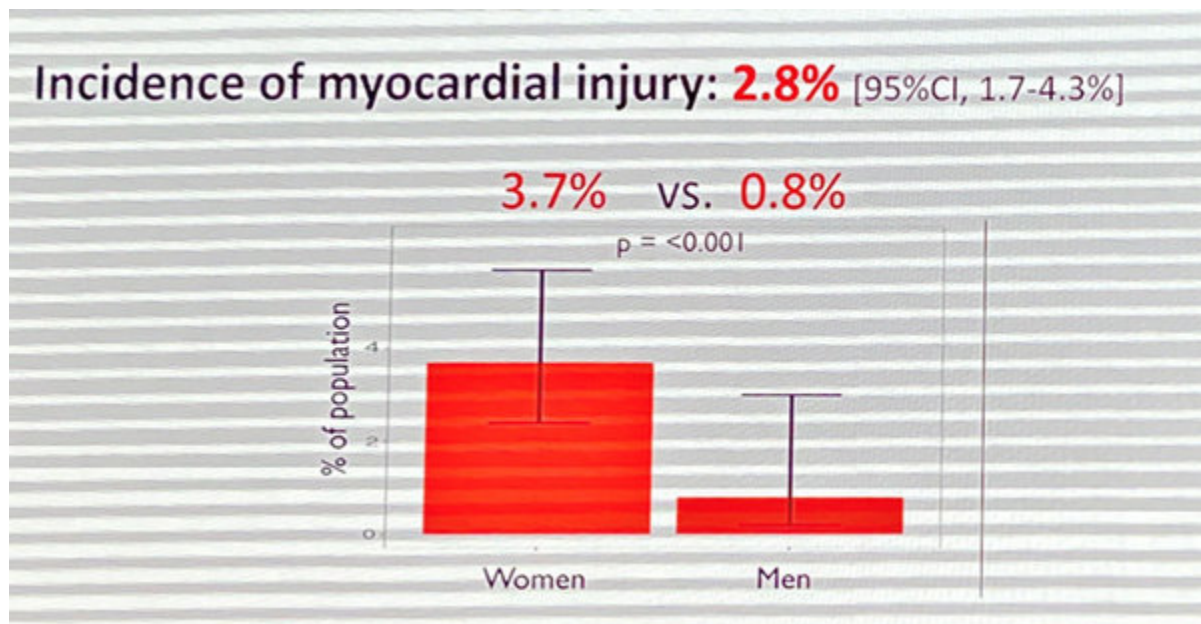


Figure 1.

This is a surprise in view of the population described in hospitalized myocarditis. When comparing the population with myocardial lesions versus the population without myocardial lesions, the only risk factor found was female gender ($p=0.03$).

The comparison with the control group found no significant difference apart from the history of myocardial infarction and peripheral atheromatous disease.

In addition, it can be noted that the troponinemia in the vaccinated population seems higher than in the control group without the statistical test having been carried out (FIG. 2).

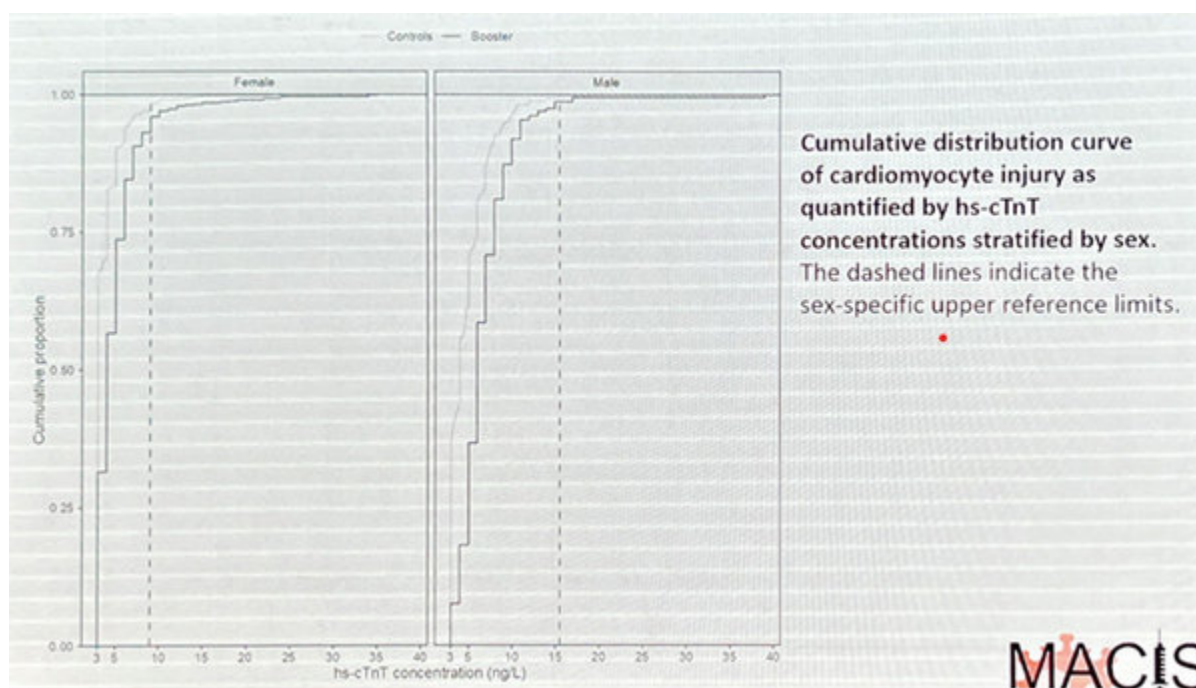


Figure 2.

Conclusion

The incidence of myocardial lesions is **2.8% or 800 times higher than the usual incidence of myocarditis**. It occurs mainly in women unlike the usual viral myocarditis.

No MACE was reported in the population studied at 30 days, however, due to repeated doses, it is interesting to wonder whether this could not lead to long-term sequelae (heart failure, arrhythmia). For this, a randomized trial with long-term follow-up would be necessary.

The limits mentioned are the achievement of troponinemia on D3, with a slight increase in troponinemia, with a possible underestimation of the incidence of early lesions on D1 potentially already normalized on D3. Moreover, in view of the slight myocardial damage, it does not seem possible to detect in cardiac MRI. Another limitation would be the absence of inclusion of patients under 18 years of age in the study population.

For more, check out the full, English-language Late-Breaking Trials presented at ESC 2022:

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The logo for AMARIN, featuring the word "AMARIN" in a blue, serif font. The letter "A" is stylized with three horizontal lines extending from its left side.The logo for sanofi, featuring the word "sanofi" in a bold, lowercase, sans-serif font. The letter "s" is black, and the letter "i" has a purple dot.