Idiopathic inflammatory myopathies linked to vaccination against SARS-CoV-2: a systematic review

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SUMMARY

The COVID-19 pandemic represents a global health problem, which has been mitigated by the opportune introduction of vaccination programs. Although we already know the benefit that vaccines provide, these are not exempt from adverse events which can be mild to deadly, such as idiopathic inflammatory myopathies, in which a temporal association has not been defined. It is for this reason that we carried out a systematic review of all reported cases of vaccination against COVID-19 and myositis.

To identify previously reported cases of idiopathic inflammatory myopathies associated with vaccination against SARS-CoV-2 we registered this protocol on the website of PROSPERO with identification number CRD42022355551. Of the 63 publications identified in MEDLINE and 117 in Scopus, 21 studies were included, reporting 31 cases of patients with vaccination-associated myositis. Most of these cases were women (61.3%); mean age was 52.3 years (range 19-76 years) and mean time of symptom onset post-vaccination was 6.8 days. More than half of the cases were associated with Comirnaty, 11 cases (35.5%) were classified as dermatomyositis, and 9 (29%) as amyopathic dermatomyositis. In 6 (19.3%) patients another probable trigger was identified. Case reports of inflammatory myopathies associated with vaccination have heterogeneous presentations without any specific characteristics: as a consequence, it is not possible to ensure a temporal association between vaccination and the development of inflammatory myopathies. Large epidemiological studies are required to determine the existence of a causal association.

Key words: *Myositis, COVID-19, vaccine, dermatomyositis, polymyositis.*

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INTRODUCTION

The SARS-CoV-2 virus is highly transmissible among humans and has become a major public health problem (1). Since the beginning of the COVID-19 pandemic, an effort has been made to decrease the rate of SARS-CoV-2 infections: more than 5.45 billion people worldwide have received a dose of a Covid-19 vaccine, equal to about 71.1% of the world population as of November 21, 2022 (2). Data shows that COVID-19 vaccines are strongly associated with the prevention of hospitalization and death in adults, especially with the addition of a booster dose (3, 4) and therefore clinicians and public health professionals should continue to promote vaccination with all recommended doses for eligible individuals (5). Some risks are associated with COVID-19 vaccines, but generally, the short-term adverse effects of COVID-19 vaccines are mild, being the most common symptoms localized pain and swelling at the injection site, fever, headache, myalgia, and chills. There are some reports of serious adverse effects related to mRNA vaccines such as myocarditis, glomerular diseases, and skin rashes. Most vaccination reactions peak within the first 6 weeks after receiving the last dose (6).

Post-vaccination autoimmunity mechanisms may be analogous to those following natural infections and biological plausibility may be based on molecular mimicry, viewer activation, the release of cryptic epitopes, activation of super antigens, direct inflammatory damage, formation of im-

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mune complexes or expression of major histocompatibility complex (MHC) antigens in non-immune cells and in patients with genetic predisposition to autoimmunity. These pathogenic mechanisms are not mutually exclusive, and anyone may be relevant depending on the stage of evolution of the disease (7).

Idiopathic inflammatory myopathies encompass a heterogeneous group of diseases that are characterized by muscle weakness, elevated serum muscle enzymes, inflammatory infiltrates in muscle biopsies, and the presence of autoantibodies. This group of diseases can be divided into polymyositis (PM), dermatomyositis (DM), inclusion body myositis (IBM), immune-mediated necrotizing myopathy (IMNM) and antisynthetase syndrome (8). Although the pathophysiological mechanisms are not fully understood and a temporal relationship between vaccination and autoimmune disorders couldn't yet be established, it is of vital importance to identify their causal relationship as well as the clinic characteristics of patients who present post-vaccination disease. There are reported cases of DM after vaccination against hepatitis B virus (HBV), mycobacterium tuberculosis, tetanus, influenza, smallpox, poliomyelitis, etc. The only case report of post-vaccination polymyositis was following the administration of the HBV vaccine. However, there is no statistically significant evidence, either prospective or retrospective, in the literature of an increase in the incidence of DM or PM after any mass vaccination program, and no meta-analyses have been published to date (9). It is for this reason that we decided to carry out a systematic literature review of all the reported cases of patients who presented a temporal association between the administration of the vaccine against COVID-19 and the subsequent development of myositis, as well as the characteristics of these patients.

METHODS

We registered this protocol on the website of PROSPERO on the 26 of August 2022 with the identification number CRD42022355551. To identify previously reported cases of idiopathic inflammatory myopathies associated with SARS-CoV-2 vaccination, a systematic review of the literature according to PRISMA guidelines was performed. MEDLINE via Pubmed and Scopus were systematically searched from the 1st of January 2020 until the 1st of September 2022. The search strategy included the following terms to identify idiopathic inflammatory myopathies cases: "myositis", "dermatomyositis", "polymyositis", "rhabdomyolysis", "antisynthetase syndrome", "inclusion body" and "immune mediated necrotizing myopathy". SARS-CoV-2 vaccination association was established with "COVID-19 vaccine", "Novavax", "NVX-CoV2373", "COVOVAX", "Nuvaxovid", "BBIBP-CorV", "COVILO", "Ad5-nCoV", "Covidencia", "BNT162b2", "Comirnaty, "ChAdOx1", "AZD1222", "Covishield", "Vaxzevria", "Ad26.COV2.S", "Jcovden", "mRNA-1273", "Spikevax", "Covaxin", and "BBV152". All terms were used to search titles and abstracts of publications.

The search was conducted as (COVID-19 vaccine OR Novavax OR NVX-CoV2373 OR COVOVAX OR Nuvaxovid OR BBIBP-CorV OR COVILO OR Ad5-nCoV OR Covidencia OR BNT162b2 OR Comirnaty OR ChAdOx1 OR AZD1222 OR Covishield OR Vaxzevria OR Ad26.COV2.S OR Jcovden OR mRNA-1273 OR Spikevax OR Covaxin OR BBV152) AND (dermatomyositis OR polymyositis OR inclusion body myositis OR immune mediated necrotizing myopathy OR antisynthetase syndrome OR rhabdomyolysis OR myositis). The database search in MEDLINE identified 63 publications, and the database search in Scopus 117, which were independently reviewed by two authors (HQM, MRHZ). A third independent reviewer (ACC) decided in case of discrepancy.

The risk of bias for each included study was assessed using the Joanna Briggs Institute Critical Appraisal checklist for case reports and case series.

After selection and evaluation, data from the included studies were extracted, including study authors and year, publications, study design, and basic information about the patients. We included all the patients

that fulfilled the 2017 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) criteria for idiopathic inflammatory myopathies, the 2013 European Neuromuscular Center (ENMC) criteria for inclusion body myositis, 2016 ENMC classification criteria for IMNM, 2018 ENMC classification criteria for dermatomyositis or the 2010 Connor´s criteria for antisynthetase syndrome and had a disease onset in temporal relation to SARS-CoV-2 vaccination. Non-English or non-Spanish articles, reviews without a description of detailed case information, and congress abstracts were excluded. Finally, 21 studies reporting 31 cases were included. The methodology flowchart is shown in Figure 1.

RESULTS

The applied vaccine and the clinical, laboratory, radiographic, and histopathologic features of SARS-CoV-vaccination-associated inflammatory myopathies of the 31 cases of the systematic review are summarized in Tables I-IV (10-31).

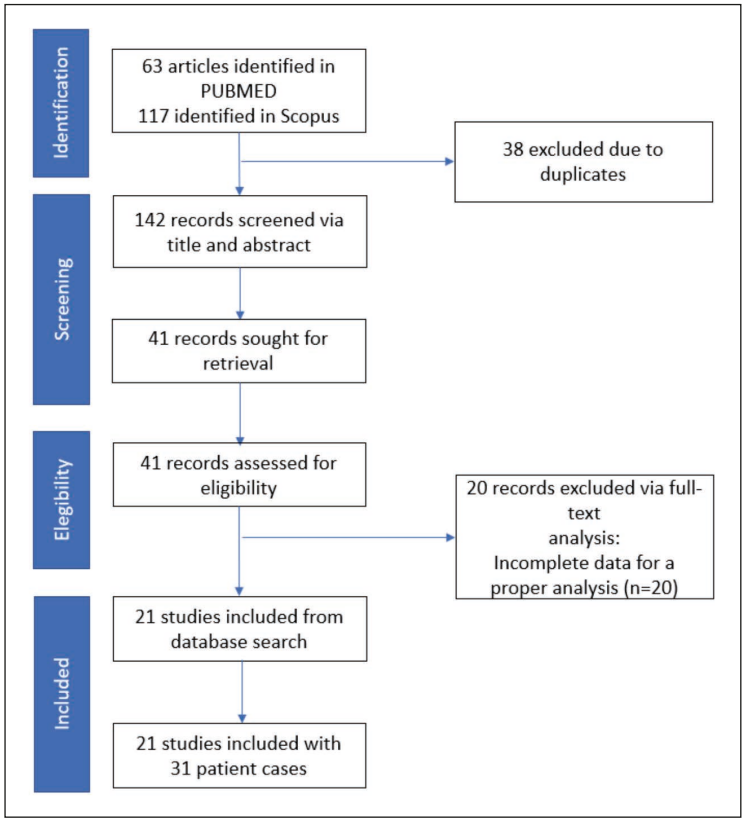

Figure 1 - Flow diagram of study selection.

Table I - Clinical findings in patients with dermatomyositis.

Author	Sex and age	Applied vaccine	Interval between application and symptoms onset	ACR/ EULAR 2017 classification	Extra-muscular or extra-skin manifestation	MSA or MAA	EMG compatible with diagnosis	Biopsy compatible with final diagnosis	Treatment	Outcome	Another possible cause
Chaima *et al.* 2022 (11)	F/52	Comirnaty (Pfizer)	7 days	Definitive DM	Polyartharlgia/ fever/abdominal pain	Negative	Yes	ND	Steroids 1 mg/kg/d	Improvement	No
Venkateswaran *et al.* 2022 (12)	M/43	Spikevax (Moderna)	1 day	Definitive DM	Dysphagia/weight loss	Negative	Yes	ND	Steroids+ IVIG	Improvement	No
Gouda *et al.* 2022 (13)	F/43	Comirnaty (Pfizer)	10 days	Probable PM (IMNM)	Arthritis/ILD/ weight loss	RNP	Yes	ND	Steroids+ MMF+HCQ	Improvement	No
Holzer *et al.* 2022 (14)	M/19	Comirnaty (Pfizer)	5 days	Definitive ADM	Arthritis/ILD	MDA5+ Ro-52	ND	Yes	Steroids+ IVIG + RTX+CYA+ Daratumumab+ Anakinra+Tofacitinib +Nintedanib	ND	No
Holzer *et al.* 2022 (14)	F/57	Comirnaty (Pfizer)	7 days	Definitive ADM	No	MDA5+ NXP2	ND	ND	Steroids+ HCQ+AZA	ND	No
Holzer *et al.* 2022 (14)	F/51	Comirnaty (Pfizer)	1 day	Probable ADM	Arthritis	MDA5	ND	ND	Steroids+HCQ+ AZA+MTX	ND	No
Aimo *et al.* 2022 (15)	F/45	Vaxzevria (Astra-Zeneca)	10 days	Definitive DM	Dysphagia	TIF-1γ	Yes	ND	Steroids+IVIG	Improvement	Cancer

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Author	Sex and age	Applied vaccine	Interval between application and symptoms onset	ACR/ EULAR 2017 classification	Extra-muscular or extra-skin manifestation	MSA or MAA	EMG compatible with diagnosis	Biopsy compatible with final diagnosis	Treatment	Outcome	Another possible cause
Magen *et al.* 2022 (16)	F/34	Comirnaty (Pfizer)	4 days	Probable PM (IMNM)	Pleural efussion/ pericardial effusion/ dysphagia/ dyspnea	Negative	Yes	Yes	Steroids+IVIG	Improvement	No
Camargo *et al.* 2022 (17)	F/76	Comirnaty (Pfizer)	1 day	Definitive DM	Dysphagia	Mi-2	Yes	Yes	Steroids+MTX	Improvement	No
Huang *et al.* 2022 (18)	M/44	Vaxzevria (Astra-Zeneca)	14 days	Probable ADM	Ascites/anuria/ metabolic acidosis	PM-Scl100	Yes	ND	Steroids+CYC	Death	No
Vutipongsatorn *et al.* 2021 (19)	F/55	Comirnaty (Pfizer)	2 days	Probable PM (IMNM)	Dyspnea	Mi-2+ Ro-52	ND	ND	Steroids+IVIG +CYC+MMF	Improvement	No
Gonzalez *et al.* 2022 (20)	M/45	Spikevax (Moderna)	2 days	Probable ADM	Arm edema/ILD	MDA5+ Ro-52	ND	ND	Steroids+ IVIG+RTX	Improvement	No
Gonzalez *et al.* 2022 (20)	F/28	Comirnaty (Pfizer)	14 days	Definitive DM	Dysphagia/ weight loss	MDA5+ TIF-1γ	ND	ND	Steroids+MMF	Improvement	No
Wu *et al.* 2022 (21)	F/77	Not specified	5 days	Probable ADM	Fever	TIF-1γ	ND	Yes	Steroids+MMF	Improvement	No
Kim *et al.* 2022 (22)	M/30	Comirnaty (Pfizer)	6 days	Definitive DM	Fever/ dysphagia/ dysarthria	ND	ND	Yes	Steroids+ TAC+AZA	Improvement	No
Kondo *et al.* 2022 (23)	F/47	Not specified	3 days	Definitive DM	Fever/ dysphagia	Negative	ND	Yes	Steroids	Not specified	No
Kondo *et al.* 2022 (23)	M/51	Not specified	6 days	Definitive DM	No	Negative	Yes	Yes	Nothing	Not specified	No
Kondo *et al.* 2022 (23)	M/26	Not specified	7 days	Probable DM	No	Negative	Yes	Yes	Nothing	Not specified	No
Lee *et al.* 2022 (24)	M/53	Comirnaty (Pfizer)	14 days	Probable PM (IMNM)	Fever/ dysphagia	NXP2	No	Yes	Steroids, IVIG, MMF, RTX	Improvement	No

F, female; M, male; ACR/EULAR, American College of Rheumatology/European League Against Rheumatism; DM, dermatomyositis; EMG, electromyography; PM, polymyositis; ADM, amyopathic dermatomyositis; IMNM, immune-mediated necrotizing myopathy; MSA, myositis-specific autoantibodies; MAA, myositis-associated autoantibodies; RNP, ribonucleoprotein; NXP2, nuclear matrix protein 2; AZA, azathioprine; CYA, cyclosporine; CYC, cyclophosphamide; HCQ, hydroxychloroquine; ILD, interstitial lung disease; IVIG, intravenous immunoglobulin; MMF, mycophenolate mofetil; MTX, methotrexate; ND, no data; RTX, rituximab; TAC, tacrolimus.

Twelve (38.7%) of the patients were male, the mean age was 52.3 years (range 19-76 years), and the mean time between the vaccination event and the onset of symptoms was 6.8 days (1-14 days).

For the associated vaccines, 18 cases (51.8%) were associated with Comirnaty (Pfizer), 4 with Vaxzevria (Astra-Zeneca), 4 (12.9%) were not identified in the case reports, 3 (9.6%) with Spikevax (Moderna), 1 (3.22%) with Jcovden (Janssen) and 1 (3.22%) with CoronaVac (Sinovac).

Twenty-six of the 31 patients were requested for myositis-specific autoantibodies (MSA) or myositis-associated autoantibodies (MAA), 7 of these 26 (26.9%) were positive for anti-MDA5, 3 (11.53%) for anti-TIF-1γ, 2 (7.6%) for anti-signal recognition particle (SRP), 2 (7.6%) for anti-Mi2, 1 (3.8%) for anti-Jo1 and 1 (3.8%) for anti-nuclear matrix protein 2 (NXP2), 8 (30.7%) were positive for MAA, 6 (23%) for anti-Ro52, 2 (7.6%) to anti- ribonucleoprotein (RNP) and 1 (3.8%) to anti-PM-Scl-100, 7 (26.9%) patients were negative for both MSA or MAA (although many were not requested for all autoantibodies). Finally, 3 patients were positive for more

than one MSA. This is highly improbable since these are usually mutually exclusive (10) so we decided to not include them in this section.

Using the 2017 EULAR/ACR criteria for inflammatory myopathies, 11 patients (35.5%) were classified as amyopathic dermatomyositis (ADM), 9 (29%) as DM, 8 (25.8%) as PM (IMNM) and 3 (9.6%) patients did not meet the criteria for immune mediated myositis (IIM). To decide the final diagnosis, we decide applied the ENMC for DM/ADM/IBM and IMNM, Connors criteria for antisynthetase, or presence of specific skin/muscle biopsy findings (like perifasciular atrophy or M×A expression). In case patients did not fulfill any of these criteria, we obtained a consensus between all authors to decide the final diagnosis. Using these criteria 19 (61.2%) patients had DM,

Table II - Clinical findings in patients with amyopathic dermatomyositis.

Author	Sex and age	Applied vaccine	Interval between application and symptoms onset	ACR/ EULAR 2017 classification	Extra-muscular or extra skin manifestation	MSA or MAA	EMG compatible with diagnosis	Biopsy compatible with final diagnosis	Treatment	Outcome	Another possible cause
Kreuter *et al.* 2022 (25)	F/68	Comirnaty (Pfizer)	8 days	Definitive ADM	No	TIF-1γ + SRP	ND	ND	Steroids	Improved	Previous cancer
Gonzalez *et al.* 2022 (20)	F/58	Vaxzevria (Astra-Zeneca)	7 days	Not meet criteria	Polyarthralgia/ dyspnea/ILD/ enlarge necrotic lymph nodes	MDA5	ND	ND	Steroids, IVIG, plasma exchange, Tofacitinib, HCQ, RTX, MMF	Improved	No
Gonzalez *et al.* 2022 (20)	F/45	Comirnaty (Pfizer)	3 days	Definitive ADM	Polyarthralgia/ fever/dyspnea/ weight loss/ILD/ facial edema	MDA5	ND	ND	Steroids, IVIG, plasma exchange, Tofacitinib, TAC RTX, MMF	Improved	No
Gonzalez *et al.* 2022 (20)	F/51	Comirnaty (Pfizer)	7 days	Definitive ADM	Polyarthralgia/ dyspnea/weight loss/arthritis/ILD	MDA5+ Ro-52	ND	ND	Steroids+ CYC	Improved	COVID-19
Gonzalez *et al.* 2022 (20)	F/54	Comirnaty (Pfizer)	14 days	Definitive ADM	Polyarthralgia	MDA5+ Ro-52	ND	ND	Steroids, MMF, AZA, MTX	Improved	COVID-19
Ooi *et al.* 2022 (26)	M/44	Spikevax (Moderna)	14 days	Probable ADM	No	TIF1-γ	ND	ND	Steroids, HCQ	Improved	COVID-19

F, female; M, male; ACR/EULAR, American College of Rheumatology/European League Against Rheumatism; ADM, amyopathic dermatomyositis; ILD, interstitial lung disease; MSA, myositis-specific autoantibodies; MAA, myositis-associated autoantibodies; EMG, electromyography; ND, no data; IVIG, intravenous immunoglobulin; HCQ, hydroxychloroquine; RTX, rituximab; MMF, mycophenolate mofetil; TAC, tacrolimus; CYC, cyclophosphamide; AZA, azathioprine; MTX, methotrexate.

Table III - Clinical findings in patients with immune-mediated necrotizing myopathy.

Author	Sex and age	Applied vaccine	Interval between application and symptoms onset	ACR/ EULAR 2017 classification	Extra-muscular manifestation	MSA or MAA	EMG compatible with diagnosis	Biopsy compatible with final diagnosis	Treatment	Outcome	Another posible cause
Durucan *et al.* 2022 (27)	M/24	Comirnaty (Pfizer)	14 days	Not meet criteria	Myocarditis/ dyspnea/ palpitations	Negative	Yes	Yes	Steroids	Improved	No
Tan *et al.* 2022 (28)	M/54	CoronaVac (Sinovac)	7 days	Probable PM (IMNM)	Dysarthria/ dysphagia	SRP	Yes	Yes	Steroids, IVIG	Improved	No
Dodig *et al.* 2021 (29)	F/55	Comirnaty (Pfizer)	1 day	Probable PM (IMNM)	Fatigue	SRP	Yes	Yes	Steroids, IVIG, MTX	Improved	No

M, male; F, female; ACR/EULAR, American College of Rheumatology/European League Against Rheumatism; MSA, myositis-specific autoantibodies; MAA, myositis-associated autoantibodies; EMG, electromyography; IMNM, immune-mediated necrotizing myopathy.

Table IV - Clinical findings in two patients with polymyositis and one patient with antisynthetase syndrome.

Author	Sex and age	Applied vaccine	Interval between application and symptoms onset	ACR/ EULAR 2017 classification	Extra-muscular manifestation	MSA or MAA	EMG compatible with diagnosis	Biopsy compatible with final diagnosis	Treatment	Outcome	Another possible cause
Vutipongsatorn *et al.* 2021 (19)	F/72	Comirnaty (Pfizer)	1 day	Not meet criteria	Anorexia	RNP	ND	ND	Steroids/ IVIG	Improved	Cancer/ Atorvastatine
Gouveia *et al.* 2022 (30)	M/49	Jcovden (Johnson and Johnson)	10 days	Definitive DM	Leg edema	ND	Yes	ND	Steroids	Improved	No
Gupta *et al.* 2021 (31)	F/46	Vaxzevria (Astra-Zeneca)	7 days	Definitive PM (IMNM)	Fever/ polyarthralgia/ ILD/dyspnea	Jo-1+ Ro-52	Yes	ND	Steroids, MTX, MMF	Improved	No

F, female; M, male; DM, dermatomyositis; PM, polymiositis; IMNM, immune-mediated necrotizing myopathy; ILD, interstitial lung disease; RNP, ribonucleoprotein; ND, no data; MSA, myositis-specific autoantibodies; MAA, myositis-associated autoantibodies; EMG, electromyography.

6 (19.3%) patients ADM, 3 (9.6%) patients IMNM, 2 (6.4%) patients PM and only one (3.22%) anti-synthetase syndrome. We could not find any IBM or juvenile dermatomyositis post-vaccine reports.

The most frequent extra-muscular/skin manifestations were dysphagia present in 9 patients (29%), followed by dyspnea in 7 patients (22.5%), fever in 7 patients (22.5%), interstitial lung disease (ILD) in 7 patients (22.5%), polyarthralgia in 6 patients (19.4%) and weight loss in 5 patients (16.12%).

At least 6 (19.3%) patients had another plausible explanation for the IIM: 4 (12.9%) had cancer at diagnosis or it was discovered during the diagnostic protocol and 2 (6.4%) had recent COVID-19 infection. These two diseases are known to be associated with IIM so they should not be ruled out as probable causative agents.

DISCUSSION

According to the present systematic review of patients with myositis after vaccination against SARS-COV 2 reported worldwide, it was found that most of the patients were women over 40 with DM, high heterogeneity in extra-muscular manifestations and positivity for myositis-specific antibodies. This is consistent with globally reported epidemiologic findings for idiopathic inflammatory myopathies (32). However, the fact that the most identified autoantibody was anti-MDA5 contrasts with what has been reported in the world literature where anti-Jo-1 is the most common in Europe and anti-Mi-2 in Mexico (33).

A rapid onset of the clinical picture was observed, contrary to the general knowledge of the classic sub-acute/chronic presentation of IIM. Few patients were asked for a panel of complete autoantibodies, highlighting the low availability of these autoantibodies in general practice.

There are already other systematic reviews on the relationship between vaccination against SARS-CoV-2 and the presentation of autoimmune diseases (including one of IIM) and like us, no unique characteristics were found between their usual presentation and the post-vaccination presentation (34-37).

Based on the reported findings, we could theorize that MII associated with vaccination is a rapid onset condition (1-14 days), with a good response to immunosuppressants and with a high rate of positivity for specific/associated myositis autoantibodies; however, no report was able to unequivocally confirm the causal association between vaccination against SARS-CoV-2 and the onset of IIM and these observations should be taken with caution.

To our knowledge, no studies indicating an increase in the incidence of inflammatory myopathies have been reported nationally or internationally after the start of the global vaccination campaign against COVID-19. On the contrary, there was a notice-

able decrease in mortality from COVID-19 (38). As a consequence, we think that the benefit of vaccination far exceeds the risk of developing MII associated with vaccination. For this reason, vaccination should continue to be promoted by all health professionals.

CONCLUSIONS

Case reports of inflammatory myopathies associated with vaccination have heterogeneous presentations, without any specific characteristics, and it is not possible to ensure an association between vaccination and the development of inflammatory myopathies. Large epidemiological studies are required to determine the existence of a such causal relationship.

Contributions
HQM, contributed to the conceptualization, methodology, writing, review, editing, and preparation of the original manuscript; MRHZ, was responsible for the conceptualization, methodology, writing, review, and editing of the report. ACC, JRHV, and MAVZ, were responsible for writing, reviewing, and editing the report.

Registration and protocol
The author registered this protocol on the website of PROSPERO on the 26 of August 2022 with an identification number of CRD42022355551.

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Conflict of interest
The authors declare no potential conflict of interest.

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