ACTA MYOLOGICA 2021; XL: p. 113-115
doi:10.36185/2532-1900-051

EDITORIAL

Unmet needs on the management of COVID-19 vaccination in patients with neuromuscular disorders

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COVID-19 outbreak has quickly reached alarming morbidity and mortality with vaccines being the only weapon to fight. Although the critical situation, no international guidelines on the vaccination management of patients with neuromuscular disorders (NMDs) has still been issued. We aimed to address some unmet needs about the management of COVID-19 vaccination in patients with NMDs.

Key words: neuromuscular disorders, COVID-19 vaccines, fever

Neuromuscular disorders (NMDs) are a heterogeneous group of genetic conditions characterized by progressive muscle degeneration and weakness. Cardiac and respiratory impairments are a common finding, which severely impact the clinical course of the disease.

There is no current evidence that patients with NMDs have a higher risk of SARS-CoV-2 infection. However, a Forced Vital Capacity (FVC) < 60%, use of invasive/non-invasive ventilation devices, presence of oropharyngeal weakness resulting in inefficient airway clearance, or systemic comorbidities, such as cardiac dysfunction, arrhythmias, diabetes and obesity, treatment with steroids or immunosuppressant drugs, are considered increasing risk factors of severe COVID-19 [1-3].

Also, fever, one of the most frequent signs of COVID-19 infections, could lead to a worse outcome in some NMDs, such as mitochondrial diseases, metabolic myopathies and myasthenia gravis, due to the risk of muscle deterioration or rhabdomyolysis [4,5]; moreover, it might induce adrenal crisis in patients on steroid treatment with a not adjusted dosage[6]. For these reasons, rapid diagnosis, isolation, and intensive clinical management are crucial for patients with NMDs who develop COVID-19.

The European Medicines Agency (EMA) approved two different types of COVID-19 vaccines: mRNA (Comirnaty - BioNTech/Pfizer and COVID-19 Vaccine Moderna) and adenoviral vectored (COVID-19 Vaccine Janssen, Vaxzevria - AstraZeneca). All of them may have several side effects, in particular fever, which accounts up to 28% and 45% after Comirnaty - BioNTech/Pfizer 1st and 2nd dose respectively; 26.7% of patients aged 18-59 and 10% of those aged > 60 years for Janssen. No data are available for Moderna and Vaxzevria - AstraZeneca) [7-10].

Patients with NMDs were not included in the vaccine trials; therefore, efficacy and safety in this population is currently unknown. NMDs are not a contraindication to vaccination for COVID-19 and, on the contrary,

Received: August 28, 2021
Accepted: September 13, 2021

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How to cite this article: Russo V, Politano L. Unmet needs on the management of COVID-19 vaccination in patients with neuromuscular disorders. Acta Myol 2021;40:113-115. https://doi.org/10.36185/2532-1900-051

COVID-19 can take a more aggressive clinical course in some patients in relation, for example, to their degree of disability. Furthermore, there is no reason to believe the vaccine will be less efficacious or safety in patients with NMDs than in the population included in COVID-19 vaccination clinical trials. Some NMDs, such as multiple sclerosis, are autoimmune disorders in which patients are not immunosuppressed, and therefore their efficiency in responding to vaccinations is well known [11]. However, drugs with immunosuppressive action can reduce antibody efficacy even though the cell-mediated response can instead be efficient and therefore guarantee the patient a certain degree of safety both for infectious risk, and for the worse evolution of the disease. At the time, there are no known serious warnings or precautions associated with the vaccines in patients with NMDs.

Italian patients with NMDs have been included by the Health Minister, into the frail category for the COVID-19 vaccination program. The inclusion in this category was also confirmed in the ordinance n. 6/2021 dated 9 April 2021 by the extraordinary Commissioner for the COVID-19 Emergency.

In our view patients with NMDs should preferentially be managed at hospital vaccination centers, so that tailored case management could be guaranteed by the neuromuscular care team, allowing for greater safety and avoiding delays in vaccination.

For patients with mitochondrial diseases, metabolic myopathies or myasthenia gravis, a prophylaxis with paracetamol 1000 mg every 6 hours, or other antipyretics, with dosage adjustment according to age, weight, kidney and liver function, within the first 24-48 hours, has been suggested in order to reduce the risk of fever [5].

For patients with NMDs and severe cardio-respiratory involvement, immunodeficiency or on immunosuppressant agents, hospitalization should be considered following the COVID-19 vaccination, as no current data regarding the efficacy and safety of COVID-19 vaccines in this subgroup of patients are available. However, a case-by-case assessment is recommended considering the age of the patients and how they previously responded to vaccination (Fig. 1).

In a recent observational study that included 658 patients receiving immunosuppressive drugs after solid organ transplantation, 46% developed no antibody response after two doses of SARS-CoV-2 mRNA vaccine [12]. Moreover, among vaccinated patients who showed no SARS-CoV-2 antibody titers after two doses of vaccine, 56% remained antibody-free 4 weeks after the third dose [13].

Anti-COVID-19 vaccination and side-effects

There is no reason to think that the side effects of the vaccine in patients with NMDs could be higher than those expected in the general population, which vary from vaccine to vaccine, and this applies to both common and rarer ones [14]. However, a transient aggravation of pre-existing symptoms during COVID-19, has been reported in patients with NMDs [15] associated with the onset of fever.

The efficacy and long-term persistence of vaccines might be lower than in normal subjects in patients with

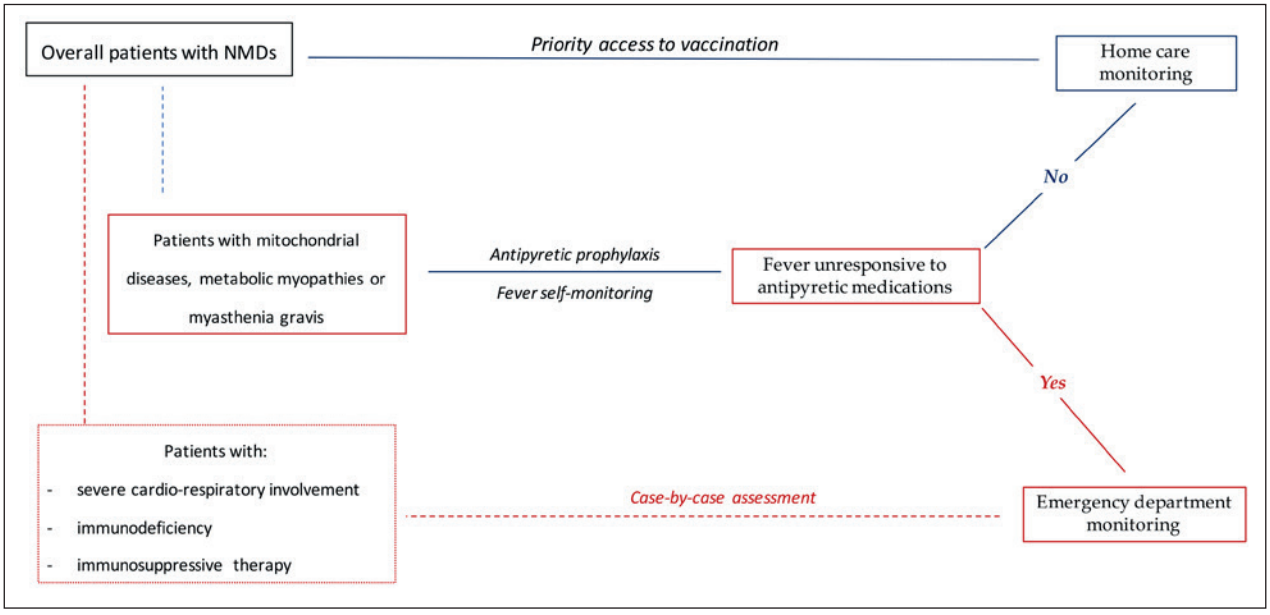

Figure 1. The workflow of the COVID-19 vaccination in patients with NMDs.

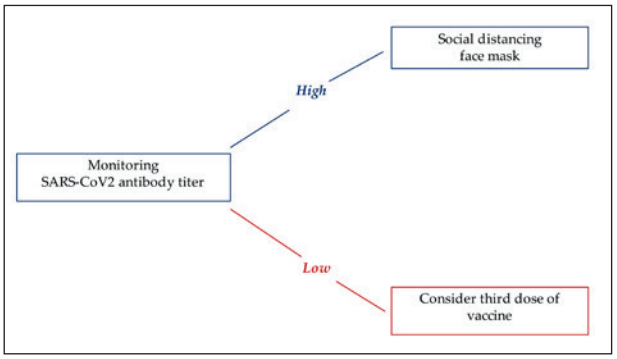

Figure 2. Vaccination monitoring in patients with NMDs and impaired immune system.

NMDs and impaired immune system [15] (Fig. 2). Therefore, we suggest monitoring the SARS-CoV-2 antibody titer to quantify the immune response and to evaluate, in selected cases, the administration of the third dose of vaccine. We also recommend the vaccination of the caregivers and of the other family members in contact with the patients.

In conclusion, we can deduce that the COVID-19 vaccination in subjects with NMDs is safe, does not generate relapses or exacerbations, as on the contrary SARS-CoV-2 infection could do. We believe that achievement of herd immunity may protect this special population as well.

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