Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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COVID-19 and vaccination against SARS-CoV-2 in patients with neuromyelitis optica spectrum disorders

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ABSTRACT

Background: Reports on outcomes of COVID-19 in patients with neuromyelitis optica spectrum disorder (NMOSD) are scarce, as well as those related to the safety profile of the vaccines in this population. The aim of this survey is to present demographic and clinical characteristics of patients with NMOSD who developed COVID-19 and safety data of the COVID-19 vaccines in these persons.

Methods: This study comprise all patients from the Hospital registry of NMOSD, of the Clinic of Neurology in Belgrade, who fulfilled the 2015 NMOSD diagnostic criteria, and who after invitation by phone call, from April 10 to May 10, 2021, accepted to participate and provide information regarding COVID-19 and vaccination against Sars-CoV-2 ($n = 53$).

Results: Sixteen out of 53 enrolled NMOSD patients were diagnosed with COVID-19. In three cases (18.8%), severity of COVID-19 clinical manifestations warranted hospitalization, and one of these patients, died due to COVID-19 (case fatality ratio = 6.25%), after invasive mechanical ventilation. The remaining two patients had grade II COVID -19 severity and were hospitalized because of pneumonia, not requiring supplemental oxygen. Median EDSS in patients requiring hospitalization was 4.5, and in the non-hospitalized group, it was 3.0. Nine out of 53 patients received two doses of vaccine against Sars-Cov-2 (8 Sinopharm and one Pfizer). Pain at the site of application was the only vaccine-related adverse effect.

Conclusions: Our survey indicates overall favourable COVID-19 outcome and encouraging safety profile of the vaccines in persons with NMOSD, in our cohort. Prospective studies are warranted to confirm these data.

1. Introduction

Neuromyelitis optica spectrum disorders (NMOSD) represent devastating neurological autoimmune disease that requires immunosuppressive treatment (Drulovic et al., 2019). It is well known that the absence or late onset of treatment with immunosuppressants is associated with a higher risk of relapses and development of accumulating disability in these patients (Drulovic et al., 2019; Kim et al., 2013). Therefore, at the present time of the COVID-19 pandemic, application of immunosupressive drugs in NMOSD presents a challenge, since evidence related to the safety of this therapeutic strategy is lacking (Salama et al., 2020). Additionally, it has been demonstrated that the higher level of neurological disability in these patients could also increase the susceptibility to serious infection (Louapre et al., 2020; Stastna et al., 2021; Alonso et al., 2021). Until now, a few studies of the prevalence of COVID-19 in immunocompromised NMOSD patients in various populations have been performed (Louapre et al., 2020; Stastna et al., 2021; Alonso et al., 2021; Sahraian et al., 2020; Ciampi et al., 2020; Fan et al., 2020).

The aim of this study was to describe cases of COVID-19 and, rate of vaccination against Sars-Cov-2 and its safety, in NMOSD patients treated and followed at the Clinic of Neurology, in Belgrade, Serbia.

2. Methods and materials

All NMOSD patients from the Hospital registry of NMOSD, of the

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Clinic of Neurology in Belgrade, who fulfilled the latest diagnostic criteria (Wingerchuk et al., 2015) were invited to participate and provide information regarding COVID-19 and vaccination against Sars-Cov-2. The Clinic of Neurology in Belgrade is the National referral center for NMOSD in Serbia. All patients were contacted by phone (several repeated phone calls for those who did not respond after the first call), from April 10 to May 10, 2021. All patients were coded and the need for informed consent was waived. In cases of reporting COVID-19 infection and/or vaccination, data were checked in the Central healthcare system registry. One hundred nineteen patients from the Hospital registry fulfilled the latest NMOSD criteria at the moment of this study (Wingerchuk et al., 2015). Thirty-five subjects from this

Table 1
Characteristics of NMOSD patients with confirmed COVID-19.

Patient	Gender	Age (year)	Antibody status	Comorbidity	NMOSD duration (years)	EDSS	NMOSD treatment	Previous contact with COVID-19 positive patient	COVID-19 symptoms	COVID-19 severity[1]	COVID-19 test
1 MB	Male	30	AQP4-IgG +	none	6.4	3.0	none	Yes	fever	I, without pneumonia	Positive antigen
2 AB	Female	35	AQP4-IgG − and MOG-IgG −	Thrombophilia	18.9	2.5	Azathioprine, 4 years before COVID-19	Not sure	fever ageusia, anosmia, headache, astenia	I, without pneumonia	Positive PCR
3 ABA	Female	25	AQP4-IgG +	Hashimoto thyroiditis	12.3	3.0	Azathioprine, 4.4 years before COVID-19	yes	fever, headache, myalgia	I, without pneumonia	Positive PCR
4 MBM	Female	60	AQP4-IgG +	Hypertension, Obesity	7.9	6.5	Inebilizumab, last dose 3 months before COVID-19	yes	fever, astenia	II	Positive antigen
5 DB	Female	64	AQP4-IgG +	Psoriasis, Hypertension	0.1	10.0	none	yes	fever, cough, astenia, digestive disorder, dyspnea	IV	Positive PCR
6 BDJ	Female	48	AQP4-IgG − and MOG-IgG −	none	17.9	8.0	MMF, 2.1 years before COVID-19	yes	cough, ageusia	I, without pneumonia	Positive PCR
7 DI	Male	61	AQP4-IgG +	Hypertension	6.5	6.0	Azathioprine, 6.2 years before COVID-19	yes	fever	I, without pneumonia	Positive PCR
8 SI	Female	61	AQP4-IgG +	SLE	4.6	8.0	none	Not sure	cought	I, without pneumonia	Not tested
9 IJ	Female	33	AQP4-IgG +	none	4.9	0	Inebilizumab, last dose 6 months before COVID-19	yes	cough, headache	II, with pneumonia	Positive antigen
10 ZJ	Female	64	AQP4-IgG +	Breast cancer	17.7	3.5	MMF, 3.4 years before COVID-19	no	fever, cough, astenia, digestive disorder	II, with pneumonia	Positive PCR
11 JK	Female	44	AQP4-IgG +	none	2.4	1.5	MMF, 1.8 years before COVID-19	Yes	ageusia, anosmia, astenia, myalgia, chest pain	I, with pneumonia	Positive antigen
12 JKJ	Female	37	AQP4-IgG +	Hashimoto thyroiditis, Latent tuberculosis	5.8	2.0	none	Yes	fever, cough	I, without pneumonia	Positive PCR
13 MM	Female	60	AQP4-IgG +	Hashimoto thyroiditis	4.4	3.5	MMF, 2 years before COVID-19	Yes	fever, ageusia, anosmia, digestive disorder	I, without pneumonia	Positive PCR
14 AM	Female	60	AQP4-IgG +	Breast cancer	0.5	8.0	none	Yes	fever, ageusia, anosmia, headache, cough, astenia	I, without pneumonia	Positive PCR
15 JR	Female	28	AQP4-IgG +	Hashimoto thyroiditis	1.9	1.0	MMF, NA	Not sure	asymptomatic	NA	SARS-CoV2 IgG +
16 VS	Male	26	AQP4-IgG +	none	11.9	2.0	MMF, 4.1 years before COVID-19	Not sure	ageusia, anosmia, astenia, fatigue	I, without pneumonia	Not tested

[1]Determined for this study.
AQP4- – aquaporin-4; EDSS – expanded disability status scale; IgG - imunoglobulin G; MOG - myelin oligodendrocyte glycoprotein antibody; MMF - Mycophenolate mofetil; NA – not applicable; NMOSD – Neuromyelitis optica spectrum disorder; SLE – Systemic lupus erithematosus.

Hospital registry were previously lost of follow-up, and 19 of them died. Twelve of these patients refused to participate in the survey, and finally, the remaining 53 were enrolled. Demographic and clinical data for these patients were extracted from the Hospital registry.

Regarding COVID-19, diagnosis was established based on a positive result of a SARS-CoV-2 polymerase chain reaction test (PCR) or positive antigen test or positive serological test. Severity score of COVID-19 was determined for this study as follows: I grade –not hospitalized, with or without evidence of pneumonia on radiography or CT scan; II grade – hospitalized, requiring or not requiring supplemental oxygen; III grade – hospitalized requiring non-invasive or invasive mechanical ventilation; IV grade – death due to COVID-19 (Table 1).

In this cohort of NMOSD patients, we also assessed the rate of vaccination against SarsCoV-2, and safety profile of COVID-19 vaccines which have been approved in Serbia (one mRNA-vaccine encoding protein S - Pfizer-BioNTech vaccine, two adenoviral vector-based vaccines: AstraZeneca and Gam-COVID-Vac–Sputnik V, and finally, inactivated vaccine developed from 2 SARS-CoV-2 strains: WIV04 and HB02, Beijing/Sinopharm BBIBP-CorV. Data about vaccination comprise: date of application of vaccine doses, type and number of doses, and vaccine-associated adverse effects and relapses. Vaccine-associated relapse was defined as relapse which occurred within at least eight weeks following an immunization.

The study was approved by the Clinic of Neurology University Clinical Center of Serbia Institutional Review Board.

2.1. Statistical analysis

Analysis includes descriptive statistics. Frequency distribution is presented as percentages and proportions. Mathematical and positional averages are shown as mean ± standard deviation (SD) and median with interquartile range (IQR).

3. Results

Sixteen out of 53 NMOSD patients were diagnosed with COVID-19. Demographic and clinical characteristics for each of these patients are presented in Table 2.

There were 13 female patients (81.3%), and 3 male patients (18.7%). Mean age was 44.7 ± 15.4 (range, 23–64) years, with mean NMOSD duration 6.6 ± 6.3 (range, 0.1–17.7) years. Median Expanded Disability Status Scale (EDSS) (Kurtzke, 1983) score was 3.0 (interquartile range, IQR = 6.0) (range, 0–10.0). One of these patients died due to COVID-19 (case fatality ratio, CFR = 6.25%). This was a 64-year-old female, who suffered from psoriasis and hypertension. She was aquaporin-4 IgG positive and had a first attack of the disease in February 2021, when the diagnosis of NMOSD was immediately established. She developed paraplegia in a few days after admission to the hospital. When she came to the Clinic of Neurology, she had no symptoms of COVID-19 and her SARS-CoV-2 PCR was negative. However, 5 days later, she was febrile and her PCR became positive, and she was transferred to the COVID center. COVID-19 symptoms were: fever, cough, asthenia, dyspnea and digestive disorders. She was on invasive mechanical ventilation. During a 3-month hospitalization, she was treated for NMOSD relapse with steroids and therapeutic plasma exchange courses. In this period, she developed COVID-19 pneumonia, urinary infection and finally sepsis. Therefore, immunosuppressants could not have been administered. She died in the beginning of May 2021. In our group, Hashimoto thyroiditis was the most common comorbidity ($n = 4$), followed by hypertension (in three patients), who were all ≥60-years old. Breast cancer in remission was present in two female patients. Obesity and thrombophilia were reported in the second and fourth patient, respectively, from the Table 2. In 5 patients NMOSD was the only diagnosis in the medical history.

Table 2
Severity score of COVID-19 infection.

I grade	Not hospitalized, with OR without evidence of pneumonia on radiography or CT scan
II grade	Hospitalized, requiring OR not requiring supplemental oxygen
III grade	Hospitalized, requiring non-invasive (high flow oxygen device) OR invasive mechanical ventilation
IV grade	Death due to COVID-19

In eleven patients, administration of immunosuppressive drugs (mycophenolate mofetil, $n = 6$; azathioprine, $n = 3$; and inebilizumab, $n = 2$) was continued in doses which were stable previously, for at least one year before COVID-19. Immunosuppressive therapy was not applied in the remaining five patients who participated in this survey, due to the fact that: one patient suffered from pulmonary tuberculosis; one patient refused immunosuppressants; and in two patients, the diagnosis of COVID-19 was recently established just prior to the diagnosis of NMOSD. Finally, as already mentioned, one patient died due to COVID-19, after repeated occurrence of various severe infections, which prevented the use of immunosuppressants.

In 11 (68.8%) cases, patients reported contact prior to the infection with person positive for Sars-CoV-2. Four (25%) patients were not sure if they had such contact and one (6.3%) patient denied that possibility.

Clinical manifestations of COVID-19 infection are presented in Table 2. The most common clinical symptoms were fever ($n = 10$), cough and asthenia ($n = 7$), ageusia ($n = 6$) and anosmia ($n = 5$).

In three (18.8%) cases, severity of COVID-19 clinical manifestations warranted hospitalization, and one of these patients, as already mentioned, died due to COVID-19, after 7 days of invasive mechanical ventilation and hemodynamic support. The remaining two patients had grade II COVID −19 and were hospitalized because of pneumonia, not requiring supplemental oxygen. In this group, all patients were female, with mean age 52.3 ± 18.5 years. Mean age in the non-hospitalized group was 42.9 ± 14.9 years. Mean disease duration in hospitalized patients was 7.0 ± 9.4 years, and in the non-hospitalized group, it was rather similar, 6.5 ± 5.9 years. Median EDSS in patients requiring hospitalization was 4.5, and in the non-hospitalized group, it was 3.0 (IQR = 5.5)

Nine out of 53 patients decided to receive two doses of vaccine against Sars-Cov-2 (Table 3). Distribution of vaccines used for our NMOSD patients is presented in Table 3. Mean age of immunized NMOSD patients was 54.3 ± 10.3 (range, 35–71) years; mean duration of NMOSD was 11.1 ± 6.3 (range, 0.9–20.3) years; median EDSS was 4.0 (IQR = 3.75) (range, 1.5–8.0). Azathioprine was maintenance treatment in seven (63%) patients, inebilizumab in one subject, and one patient refused to take immunosuppressants, already before pandemic of COVID-19. Sinopharm vaccine was predominantly applied in our patients ($n = 8$); one patient received Pfizer-BioNTech vaccine. No immunized patients had severe vaccine-associated adverse effects. Pain at the site of application was the only vaccine-related adverse effect, observed in this study. No patients reported new or worsening neurological symptoms following the vaccination. After at least two months of follow-up, no vaccine-associated NMOSD relapse was confirmed. One of 9 immunized patients suffered from COVID-19, five months before vaccination.

4. Discussion

We analysed COVID-19 and vaccination against SarsCoV-2 in 53 NMOSD patients, diagnosed according to the revised 2015 criteria, using the NMOSD Hospital registry (Wingerchuk et al., 2015). Our data showed that 16/53 (30.2%) patients developed COVID-19. Similar to our results, predominance of women, which could be explained with the well-known data that NMOSD affects women more frequently than men (Pandit et al., 2015), was also demonstrated in the French (Louapre et al., 2020), Czech (Stastna et al., 2021) and Iranian cohort of NMOSD patients with COVID-19 (Sahraian et al., 2020). Having in mind, chronic neurological disability and maintenance immunosuppressive therapy in

Table 3
Characteristics of NMOSD patients vaccinated against Sars-Cov-2, vaccination-associated side effects and relapses.

Gender	Gender	Age (years)	Antibody status	Comorbidity	NMOSD duration, before vaccination	EDSS	NMOSD treatment, before first dose of vaccine, duration/last dose	Previous COVID-19	Vaccine	Side effects	Vaccine-associated NMOSD relapse, follow-up time
1 AB	Female	35	AQP4-IgG − and MOG-IgG −	Thrombophilia	18.9	2.5	Azathioprine, 4 years	Yes, 5 months before	Beijing/ Sinopharm BBIBP-CorV	none	No, 7 months
2 KC	Female	53	AQP4-IgG − and MOG-IgG −	None	15	6.5	none	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 2 months
3 DI	Male	61	AQP4-IgG +	Hypertension	6.4	6.0	Azathioprine, 6.2 years	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 3 months
4 SM	Female	55	AQP4-IgG +	none	0.9	4.0	Azathioprine, 0.7 years	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 5 monts
5 LJM	Female	71	AQP4-IgG +	Hypertension, Ostheoporosis	11.5	3.5	Inebilizumab, last dose 7 months before first dose of vaccine	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 5 months
6 BM	Male	44	AQP4-IgG −	Hypertension, Diabetes type II	9.3	4.0	Azathioprine, 9.1 years	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 4 months
7 MS	Female	56	AQP4-IgG +	Schizophrenia, COPD, Latent tuberculosis, Reccurent deep venous thrombosis	6.5	8.0	Azathioprine, 1.7 years	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 3 months
8 ZS	Male	61	AQP4-IgG +	Hypertension, Depression	11	1.5	Azathioprine, 8.2 years	no	Beijing/ Sinopharm BBIBP-CorV	none	No, 5 months
9 DS	Female	53	AQP4-IgG +	Hashimoto thyreoiditis, Depression, Ostheoporosis	20.3	2.5	Azathioprine, 6.6 years	no	Pfizer-BioNTech	Pain on site of application	No, 5 months

AQP4- – aquaporin-4; COPD - chronic obstructive pulmonary disease; EDSS – expanded disability status scale; IgG - imunoglobulin G; NMOSD – Neuromyelitis optica spectrum disorder.

NMOSD, these patients are at higher risk of COVID-19 (Hamdy et al., 2020). Moreover, older age, shorter disease duration and higher disability, measured by EDSS, have been demonstrated in the multi-center French NMOSD study, to influence susceptibility to develop severe COVID-19 (Louapre et al., 2020). Older age and increased EDSS were also associated with hospitalization/intensive care unit in sixteen NMOSD patients with COVID-19 from a Latin America registry of MS and NMOSD patients infected with COVID-19 (Alonso et al., 2021). Similarly, in our study, in three (18.8%) NMOSD cases whose severity of clinical manifestations warranted hospitalization, mean age and median EDSS were higher in comparison to non-hospitalized patients. Due to the small number of subjects, statistical analyses could not have been performed. Unfortunately, one of these patients with high level of disability (EDSS=8.0) at relapse nadir, died during this first NMOSD relapse, due to COVID-19. Similarly, in a multicentric online national survey in Chile, out of 4 NMOSD patients with COVID-19, one patient, with EDSS 6.0 and disease duration 0.3 years, had also a fatal outcome, due to secondary bacterial infection. These unfavourable clinical outcomes might be potentially explained, at least partially, with an impact of higher neurological disability during relapse at NMOSD onset in both cases (Ciampi et al., 2020). Poor outcome in NMOSD patients with COVID-19 disease was also demonstrated in the study performed in Czech Republic, in which 4 NMOSD patients (30.77%) had severe COVID-19 and two patients (15.4%) died (Stastna et al., 2021). In our cohort, case fatality ratio was lower (CFR = 6.25%). Immunosuppressive therapy, which is in general a risk factor for infection, including COVID-19 (Abboud et al., 2020), was stable for at least one year before COVID-19, in our 11 patients. Until now, there is no clear evidence implicating relationship between any specific disease-modifying therapy and severity of COVID-19 in NMOSD patients (Salama et al., 2020; Sahraian et al., 2020; Ciampi et al., 2020). Large Chinese cohort of NMOSD patients (n = 3060), in which 69.6% patients were using a disease-modifying therapy did not demonstrate increased risk of COVID-19 regardless of therapeutic regimen (Fan et al., 2020). However, recently, it has been demonstrated in the French cohort that all five patients with NMOSD and COVID-19 who required hospitalization were treated with rituximab (Louapre et al., 2020). In our cohort, one of the patients who were hospitalized was treated with mycophenolate mofetil, one with inebilizumab, and the patient who died during hospitalization was not treated with immunosuppressant. It has to be emphasized that none of our interviewed patients had ever considered stopping maintenance treatment.

Until now, evidence related to the safety profile of the COVID-19 vaccine in NMOSD is limited. Very recently, an anonymous survey was distributed to patients with rare neuroimmuological diseases, recruited on social media, to report real-world safety data of the COVID-19 vaccines. 242 participants reported NMOSD, and the most common described adverse events were local reactions, including, most frequently, injection-site pain (Lotan et al., 2021). Similarly, in our study, in which nine out of 53 patients received vaccine against SARS-CoV-2 (8 Sinopharm and one Pfizer), the only adverse event frequently stated was pain at the site of application. After follow-up

period of at least 8 weeks, the only reported adverse event was also injection site pain. Additionally, none of our patients had either vaccine-associated serious adverse effects or vaccine-associated NMOSD relapse. Thus, these data are completely in line with previously mentioned survey which indicates an overall favourable safety and tolerability profile of the COVID-19 vaccines among persons with NMOSD. It is quite clear that these data have to be confirmed in prospective cohort studies.

In conclusion, we have demonstrated an overall favourable COVID-19 outcome in our representative cohort based on the Hospital NMOSD registry. Although, we have found older age, shorter disease duration and increased EDSS in the limited number of NMOSD patients, as factors associated with severe COVID-19, larger prospective studies are needed to confirm these data. We have also provided preliminary findings implicating favourable safety profile of vaccines against SarsCov-2 in this immunocompromised population.

CRediT authorship contribution statement

Vanja Jovicevic: Writing – original draft, Investigation, Visualization, Writing – review & editing. **Jovana Ivanovic:** Data curation. **Marko Andabaka:** Data curation, Investigation. **Olivera Tamas:** Data curation, Investigation. **Nikola Veselinovic:** Data curation, Investigation. **Nikola Momcilovic:** Data curation, Investigation. **Sarlota Mesaros:** Conceptualization, Investigation. **Tatjana Pekmezovic:** Conceptualization, Formal analysis, Methodology. **Jelena Drulovic:** Conceptualization, Writing – original draft, Writing – review & editing.

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