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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 immuno-suppressive 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 immunosuppressive 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
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 | 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 +    | 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, fever, astenia | 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, cough, astenia, digestive disorder, dyspnea | II | Positive antigen  |
| 5 DB    | Female | 64         | AQP4-IgG +    | Psooriasis, Hypertension | 0.1  | 10.0 | none | yes | fever, cough, ageusia, anosmia, digestive disorder | IV | Positive PCR  |
| 6 BDJ   | Female | 48         | AQP4-IgG +    | none | 17.9 | 8.0 | MMF, 2.1 years before COVID-19 | yes | cough, ageusia | I, without pneumonia | Positive PCR  |
| 7 DJ    | 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 | cough | I, without pneumonia | Not tested | Positive antigen  |
| 9 LJ    | Female | 33         | AQP4-IgG +    | none | 4.9 | 0 | Inebilizumab, last dose 6 months before COVID-19 | yes | cough, headache | II | with pneumonia | Positive PCR  |
| 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 | fever, cough, ageusia, anosmia, myalgia, chest pain | I, with pneumonia | Positive antigen  |
| 12 JKL  | 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 | anaemia, anosmia, fatigue | NA | SARS-CoV2 IgG + Not tested |
| 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 | Positive PCR  |

1 Determined for this study.
AQP4 – aquaporin-4; EDSS – expanded disability status scale; IgG – immunoglobulin G; MOG – myelin oligodendrocyte glycoprotein antibody; MMF – Mycophenolate mofetil; NA – not applicable; NMOSD – Neuromyelitis optica spectrum disorder; SLE – Systemic lupus eritematosus.
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 Sars-CoV-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: AstraZenea and Gam-COVID-Vac-Sputnik V, and finally, inactivated vaccine developed from 2 SARS-CoV-2 strains: WIV04 and HB02, Beijing/Sinopharm BIBP-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 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.

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 (Louandre 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 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 |
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 neurological disability during relapse at NMOSD onset in both cases (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; Sabratan 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 treatment, before first dose of vaccine.

Table 3

| 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 DJ   | 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 months                                 |
| 5 LJM  | Female | 71          | AQP4-IgG + | Hypertension, Osteoporosis | 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 – and MOG-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, Recurrent 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 thryeoiditis, Depression, Osteoporosis | 20.3                             | 2.5  | Azathioprine, 6.6 years                          | no              | Pfizer-BioNTech | Pain on site 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.
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.

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