Optic neuropathy following COVID-19 vaccine

Neuropatia óptica após a vacina contra a COVID-19

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ABSTRACT

This case series describes four patients who presented with retinal and optic nerve vascular occlusions after administration of different COVID-19 vaccines. The first patient received the ChAdOx1 nCoV-19 vaccine (AZD1222; Oxford/AstraZeneca) and 42 days later developed central retinal artery occlusion. The second patient developed a painless visual impairment in the left eye and was diagnosed with anterior ischemic optic neuropathy 6 days after receiving the Sinovac-CoronaVac vaccine. The third patient presented with the same condition 22 days after receiving the third dose of the COVID-19 Pfizer (Comirnaty®) vaccine. The fourth patient developed bilateral retrobulbar optic neuritis after receiving the Oxford/AstraZeneca vaccine. The purpose of this case series is to discuss the possibility of a causal association between ischemic eye alterations and COVID-19 virus vaccination. Long-term follow-up and evaluation of similar cases will help elucidate the degree of the association between the vaccine and ischemic ocular events.

RESUMO

Esta série de casos descreve quatro casos de pacientes que apresentaram oclusões vasculares de retina e nervo óptico após a administração de tipos diferentes de vacinas contra COVID-19. O primeiro paciente tomou a vacina ChAdOx1 nCoV-19 (AZD1222; Oxford/AstraZeneca) e 42 dias depois desenvolveu oclusão da artéria central da retina. O segundo paciente teve défice visual indolor no olho esquerdo após 6 dias da vacina Sinovac (CoronaVac) e foi diagnosticado com neuropatia óptica isquêmica anterior. O terceiro paciente apresentou o mesmo quadro após 22 dias da terceira dose da vacina COVID-19 Pfizer (Comirnaty®). O quarto paciente desenvolveu neurite óptica retrobulbar bilateral após vacina Oxford/AstraZeneca. O objetivo da nossa série de casos é discutir a possibilidade de correlação entre os quadros oculares isquêmicos e a vacinação contra a COVID-19. Nossos pacientes receberam vacinas contra COVID-19 com tecnologias diferentes e apresentaram quadros isquêmicos oculares relacionados temporalmente à vacinação. O acompanhamento e a avaliação a longo prazo de novos estudos semelhantes elucidarão o grau de associação entre a vacina e esse possível evento adverso.

INTRODUCTION

Since the emergence of the coronavirus disease (COVID-19), our understanding of its pathogenic effects continues to grow. This virus causes a severe acute respiratory syndrome and reaches cells through the angiotensin-converting enzyme 2 (ACE2) receptor.[1] The most common ocular complication is conjunctivitis. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been localized in tear secretion and lacrimal fluids, which are considered one of the ways of disease transmission.[2,3]

The ACE2 is a functional receptor on cell surfaces that is responsible for maintaining balance in the renin-angiotensin system.[4] Patients with COVID-19 have depletion of ACE2 function, and therefore reduced vasoprotection.[5] Studies have shown that COVID-19 is associated with inflammation-induced hemostatic malfunction, endothelial damage, and severe coagulopathy with a procoagulant tendency, which predisposes patients to arterial and venous thrombotic disease.[6-8]

However, a study of 434,515 patients diagnosed with COVID-19 recently reported a higher rate of retinal thromboembolic episodes after infection, mainly venous versus arterial events.[6] Although a cause-and-effect relationship cannot be established in such a retrospective study, the notion is supported by what we know about COVID-19 and reduced vasoprotection.[6]

Currently, there has been a tremendous increase in reports of ophthalmic manifestations related with COVID-19 and, presumably, its vaccination, including anterior ischemic optic neuropathy (AION).[7] This case series presents four patients whom developed ischemic vasculopathy affecting the retina and optic nerve following vaccination for Covid-19. The type of COVID-19 vaccination varied between patients. Our objective is to discuss whether there may be a causal relationship between COVID-19 vaccination and the development of ischemic ocular disease due to the pro-inflammatory state after vaccine exposure.

CASE REPORTS

Case 1

A 62-year-old female patient was admitted on March 18, 2021, with a sudden decline in visual acuity in the left eye for 4 days without pain or other associated symptoms. At presentation, she had a best corrected visual acuity (BCVA) of 20/20 on the right eye (OD) and 20/400 on the left eye (OS). She denied having any systemic diseases. She had received the ChAdOx1 nCoV-19 (Oxford/AstraZeneca) vaccine 42 days prior to presentation.

Direct and indirect pupillary reflexes were decreased OS. Slit lamp biomicroscopy was within normal limits in both eyes (OU). On fundoscopy, OD was within normal limits, but retinal pallor and the presence of an atrophic scar in the inferior temporal arcade was diagnosed OS (Figure 1). Fluorescein angiography showed a significant delay in retinal arterial filling OS (Figure 1).

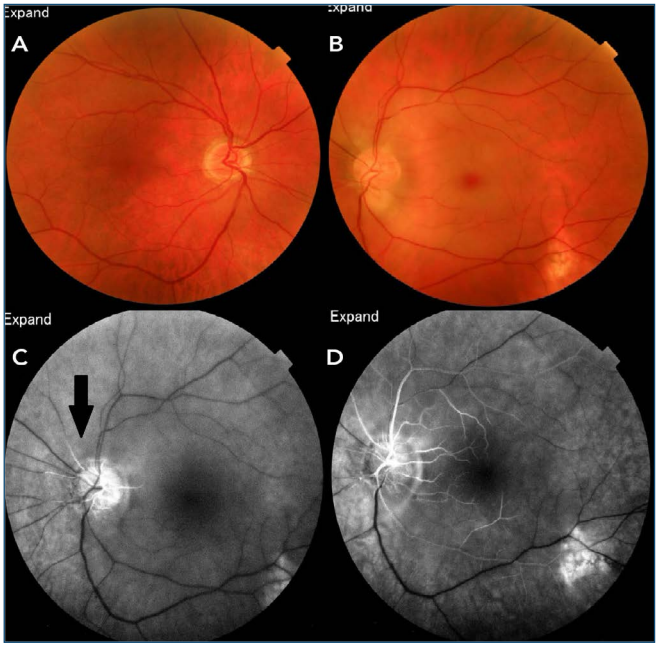

Figure 1. Funduscopic color images. (A) Right eye is within normal limits. (B) Left eye shows retinal pallor, a cherry fovea, and peripapillary chorioretinal atrophy and inferior temporal arcade. Fluorescein angiography of the fundus left eye revealed. (C) A delay in retinal arterial filling after choroidal flush. Areas where arteriole filling is partial and slowed suggested lumen partial obstruction (arrow). A systemic evaluation was performed, identifying a platelet count of 298,000mm³. Serological testing for infectious organisms was unremarkable. Carotid Doppler ultrasonography revealed no abnormalities. The patient was referred for follow-up and a complete cardiovascular investigation. Clinical follow-up revealed no change in her ocular or visual condition. (D) Slow filling of the arterioles and partial filling of the veins of the superior temporal arcade.

Case 2

A 73-year-old male patient presented with visual difficulty OS on April 19, 2021 without pain or other associated symptoms aside from occasional migraine headaches. He reported having received the Sinovac-CoronaVac vaccine on March 24, 2021. Previously reported systemic comorbidities included systemic arterial hypertension (currently under treatment), dyslipidemia, hepatic steatosis, and benign prostatic hyperplasia. Ophthalmologic history included ocular trauma OD that progressed to cataracts, retinal detachment, and visual loss.

On initial examination, direct and indirect pupillary light reflexes were unchanged OS. He had a BCVA of without light perception OD and 20/400 OS. Biomicroscopy, color retinography, and macular optical coherence tomography were without detectable abnormalities OS. On April 24, 2021, the patient underwent nuclear magnetic resonance imaging of the cranium, and changes suggestive of optic nerve involvement were detected. On May 7, 2021, fluorescein angiography revealed progressive hyperfluorescence of the optic disc OS.

The patient was submitted to a systemic evaluation. A complete blood count (CBC) was within normal limits, serum cholesterol was 248mg/dL, low density lipoprotein (LDL) was 179mg/dL, high density lipoprotein (HDL) was 18mg/dL, serum creatinine was 0.9mg/dL, and thyroid hormone, homocysteine, prostate specific antigen (PSA), partial urine sample, and liver enzymes were all normal. Inflammatory markers were normal to slightly low with an erythrocyte sedimentation rate of 39mm/h and a C-reactive protein of 1.7mg/dL. Serological infectious agents were negative.

The patient was referred for follow-up and a complete cardiovascular investigation and management. A diagnosis of late-onset neuromyelitis optic spectrum disorder (VLO-NMOSD) with positive aquaporin 4 (AQP4) was made, and he underwent pulse therapy and oral treatment with azathioprine.

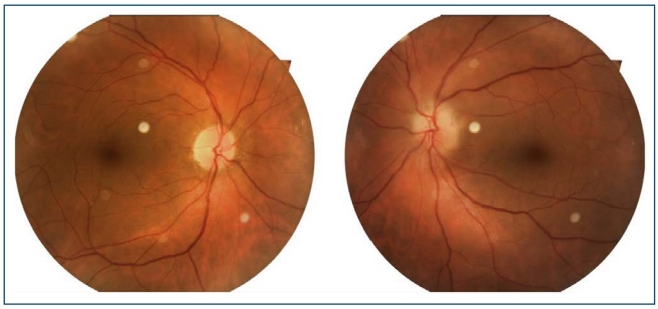

Figure 2. Optic disc swelling and blurred disc margins in the left eye.

Case 3

A 58-year-old female patient was admitted on January 18, 2022 with sudden low visual acuity OS for 5 days, without pain or other associated symptoms. She had a BCVA of 20/25 OD and 20/20 OS. The patient denies any systemic diseases and reports having received the third Pfizer-Comirnaty® vaccine on December 22, 2021.

Biomicroscopic examination revealed a clear cornea, trophic iris, and intraocular lens OU. On fundoscopy, a normal retina and unchanged macula were observed, although blurring of the optic disc edges OS were suggestive of papilla edema (as shown in Figure 2). Magnetic resonance imaging of the cranium and carotid Doppler ultrasound showed no abnormalities. On January 31, 2022, a 24-2 Humphrey computerized visual field exam revealed an inferior altitudinal field defect (Figure 3), suggestive of anterior ischemic optic neuritis.

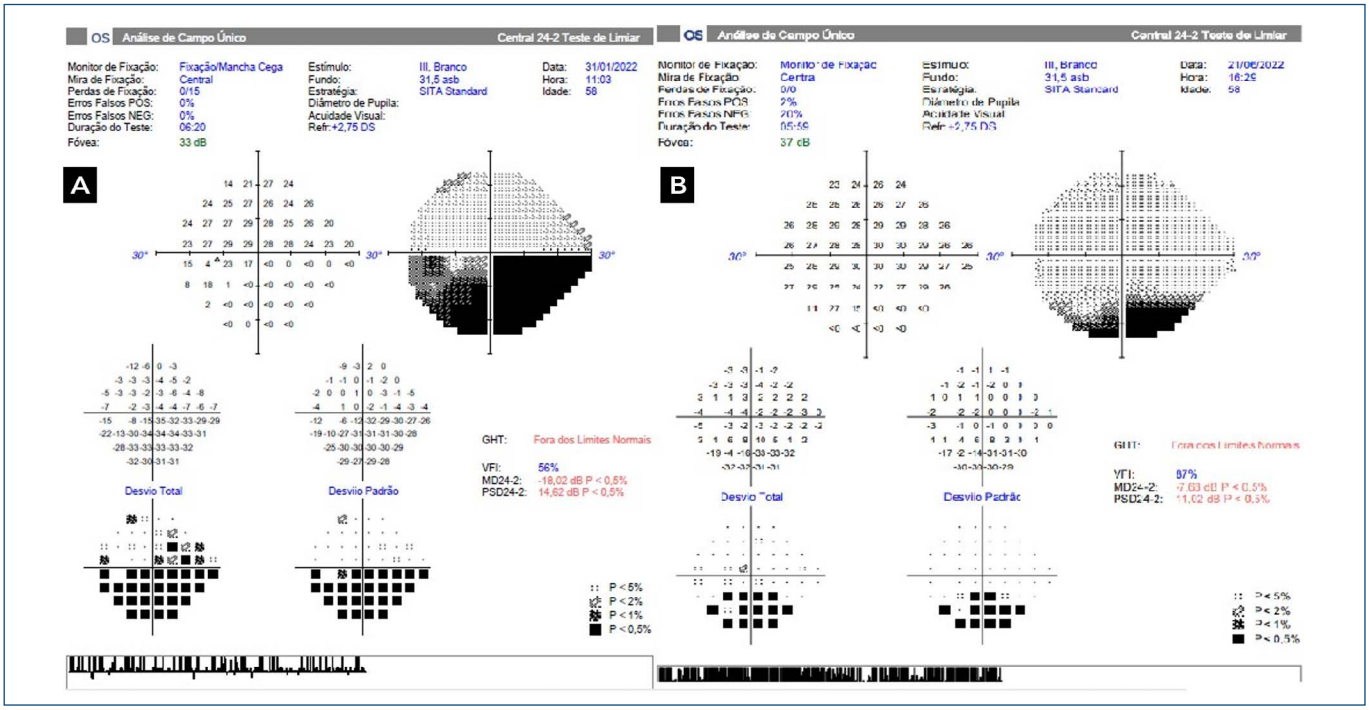

Figure 3. 24-2 Humphrey computerized visual field exam. (A) Inferior altitudinal field defect in the left eye. (B) A significant visual field recovery is observed 5 months after the first examination.

On January 25, 2022, systemic investigation detected on CBC a total leukocyte counts of 17.200/mL^3 with a predominance of neutrophils, a hemoglobin of 14.3g/dL, and a platelet count of 346 thousand/mL^3, without other changes. Serological infectious agents were negative. Erythrocyte sedimentation rate was 9mm/h and C-reactive protein was less than 1.0mg/dL. On February 1, 2022, a repeated platelet count detected 438.600/mL^3.

The patient was referred for follow-up and a complete cardiovascular investigation. The patient continued her follow-up with significant visual acuity and visual field recovery as shown in figure 3.

Case 4

A 67-year-old female patient was admitted on May 05, 2021, with ocular pain OD for 5 days associated with vision shadowing and pain when moving the eye, without other symptoms. She had a without corrected visual acuity of 20/70 OD and 20/20 OS. She denied having any systemic diseases. She had received the AstraZeneca vaccine 21 days prior to presentation.

Examination revelated a relative afferent pupillary defect (0.6 log) and altered color vision OD. Slit lamp biomicroscopy and fundoscopy (including macula, retinal vessels, and optic nerve) were unchanged OU. Optical coherence tomography (Spectralis® Heidelberg Engineering) of the optic nerve revealed a normal layer of nerve fibers and ganglion cells OU. A reverse visual pattern evoked potential test showed discretely reduced amplitudes with increased latency OD, suggestive of retrobulbar optic neuritis (Figure 4). Magnetic resonance imaging showed thickening of the intra-orbital segment of the optic nerve OD with enhancement after gadolinium contrast, suggestive of optic neuritis or perineritis (Figure 5).

After 4 months, the patient was given another dose of the AstraZeneca vaccine and developed similar symptoms OS after 1 month. She underwent another magnetic resonance imaging scan, which found similar signs suggestive of optic neuritis or perineuritis OS (Figure 5). The patient was submitted to a systemic investigation, and a CBC was unchanged with a negative infectious serological investigation.

DISCUSSION

COVID-19 disease is relatively new and is not yet completely understood. It primarily affects the airways but can affect many different body systems by different mechanisms that have not yet been fully elucidated. It is known

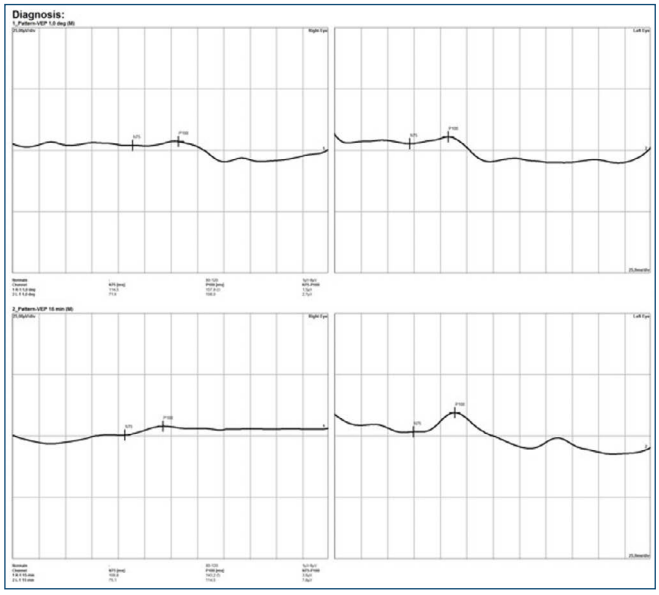

Figure 4. The reverse visual pattern evoked potential test showing discretely reduced amplitudes with increased latency on the right eye.

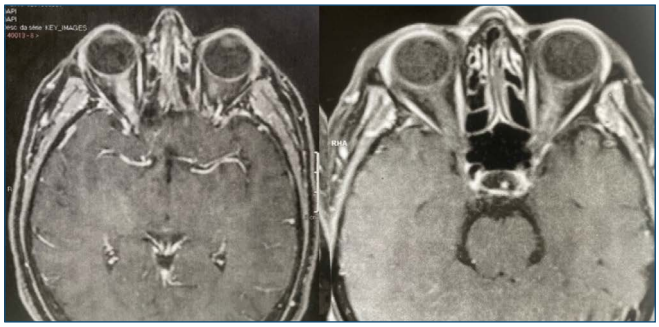

Figure 5. In the nuclear magnetic resonance scan on the left, taken in May 2022, diffuse thickening of the intraorbital segment of the right optic nerve is evident. In the image on the right, taken in September 2022, diffuse intraorbital thickening of the left optic nerve is evident. Findings are suggestive of retrobulbar optic neuritis.

that a pro-coagulant state is observed in some patients who are affected, including prolonged prothrombin time, elevated D-dimers, and increased concentrations of cytokines and pro-inflammatory biomarkers that increase the likelihood of disseminated intravascular coagulation and thrombotic microangiopathy.[8]

The virulence and transmissibility of COVID-19 brought about a critical need for efficient vaccines against the disease. The approval processes for any potential experimental COVID-19 vaccine were unquestionably different from those of previous vaccine or drug authorizations. Correspondingly, adverse reactions following vaccination had not been entirely documented prior to mass release and administration, and thus new sequelae continue to emerge post-vaccination.

COVID-19 vaccinations differ mechanistically in how they help develop partial immunity to the virus. The Coronavac vaccine, developed by Sinovac Life Sciences (Beijing, China), is based on the inactivated whole SARS-CoV-2 virus that is unable to replicate or cause disease in the host, only triggering cellular and humoral immune responses. In this case, the suggested mechanism for the procoagulant state would be related to the COVID-19 virus itself and the immune response triggered in the body. In contrast, the Pfizer-BioNTech COVID-19 Vaccine (also known as Comirnaty) relies on messenger RNA (mRNA), produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein. After entering the human cell, the mRNA S protein will start to be produced by human cells for which an immune response will be then developed.[9]

There is no specific guidance from the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) for mRNA vaccine products. However, the growing number of clinical trials carried out under EMA and FDA supervision indicates that regulators have accepted the proposed approaches. mRNA production avoids the common risks associated with other vaccine platforms, including live viruses, viral vectors, inactivated viruses, and protein subunit vaccines. In vaccinated people, the theoretical risks of infection or integration of the vector into the DNA of the host cell are not a concern for mRNA. For the above reasons, mRNA vaccines have been considered a relatively safe vaccine format.[10]

However, numerous reports suggest a correlation between mRNA-based vaccines and the development of autoimmune diseases. The pathophysiology could be related to molecular mimicry between the adjuvant present in the vaccine and its similarity to autoantigens or hyperstimulation.[11] Another possible concern is the impact that free RNA in the plasma can have on blood components, possibly resulting in thromboembolic events.[12] A study in mice found that extracellular RNA is a procoagulant factor for thrombus formation. Hepatitis C virus RNA radiolabeled to individual coagulation proteins revealed strong interactions between factors XII or XI and the RNA, while prekallikrein and kininogen showed weaker binding.

The Oxford/AstraZeneca vaccine is based on the virus vector and has been shown to be associated with an immunological thrombosis similar to heparin-induced thrombocytopenia (HIT) and is called vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). A possible explanation for this state of disseminated intravascular coagulation could be the presence of free DNA particles in the vaccine that bind to platelet factor 4 (PF4) and trigger autoantibodies reactive to PF4 in the serum.[13] It is unknown whether VIPIT, like HIT, is associated with arterial thrombosis, but arterial clots should be considered if patients have consistent symptoms.[14] We exclude the possibility that the patient in case 1 presented with the condition of VIPIT, as she does not fit the required criteria. She presented with blurred vision 42 days after her first dose of the Oxford/AstraZeneca vaccine. Although the symptoms were consistent with those listed in the proposed criteria for the disease, the time since vaccination, the patient's platelet count and age speak against VIPIT.

Most published thrombotic complications are related to the Oxford/AstraZeneca vaccine,[2] however one report of a young male patient who developed combined retinal artery and central vein occlusion after a second dose of the mRNA BNT162b2 (Pfizer/BioNTech) vaccine has been described.[15] The patient had uncontrolled blood pressure and high cholesterol levels. The authors suggest that the immunological inflammatory process associated with hypercoagulability in patients with cardiovascular comorbidities increases the risk of thromboembolism.[15] Another series of cases described 11 patients who had retinal arterial occlusion, venous or nonspecific vascular changes. The patients had received different types of vaccinations. Importantly, 7 of the 11 patients did not have additional cardiovascular risk factors.[16]

It is still questionable whether the occurrence of ocular ischemic disease during or after COVID-19 vaccination is coincidental or not. A retrospective study found no evidence for association between COVID-19 vaccination and an increased risk of retinal vascular occlusive disease (odds ratio, OR = 0,93; 95% confidence interval, 95%CI 0,60-1,45; p=0,75).[17] However, in a report of a patient with anterior ischemic optic neuritis associated with COVID-19, the patient evolved with a systemic presentation of COVID-19 associated with visual blurring. Fundus photography revealed signs of hypertensive retinopathy, hemorrhages in the posterior pole, and papillary edema. The authors suggest a direct relationship of the infection with the ocular symptoms, due to the state of hypercoagulability and low oxygenation already well established by infection with the COVID-19 virus.[18] Additionally, a large retrospective cohort study involving 7,318,437 patients found that the overall risk of retinal vascular occlusion in the vaccinated cohort was 2.19 times higher than that of the unvaccinated cohort at 2 years (95%Cl 2.00-2.39).[19]

Case 1 in the present report may represent a greater potential for coincidence or summation of risk factors that contributed to ocular manifestation of the disease.

Three patients in the present report were diagnosed with optics neuritis following vaccination against COVID-19 (CoronaVac, Pfizer and AstraZeneca). Vaccine-induced prothrombotic immune thrombocytopenia was excluded because the patients had platelets within the normal range. In general, COVID-19 vaccination results in a high level of neutralizing antibodies that target and inactivate the viral S proteins before viral dissemination and consequent illness.[20] In some patients, after vaccination, antibodies against S proteins and/or activated T-helper-1 cells may cross-react with the patients' own proteins and antigens, especially in large arteries, outer retinal layers, and retinal pigment epithelial cell.[20] Thus, antigenic mimicry between viral and human proteins may explain a biological plausibility for COVID -19-vaccine associated adverse effects, elucidating the clinical presentation of potential ophthalmological complications, particularly for the optic nerve. There is a possibility for the same pathophysiology be responsible for some of the cases of retinal and optic nerve changes observed in some patients during COVID-19.[7] Although it is not possible to establish the exact nature of the findings, the evolutionary pattern and distribution characteristics of the lesions may suggest inflammatory disease related to Immunoglobulin G of the myelin oligodendrocyte glycoprotein (MOG) (also called MOG antibody-associated disease) occurring in a post-vaccination environment in case 4. Meanwhile, in case 2, the autoantibody (NMO-IgG) was detected, which binds to the AQP4 channel, mainly affecting the optic nerve.

In conclusion, the present study suggests at least a coincidental relationship or a sum of risk factors for optic neuropathy and COVID-19 vaccination. Patients with well-established cardiovascular risk factors, such as systemic arterial hypertension, atherosclerosis, and dyslipidemia, or conditions associated with a pro-inflammatory state, may be at an increased risk for succumbing to an occlusive vascular event following COVID-19 infection or vaccination. Additionally, antigenic mimicry may impact the cardiovascular system or the neural layer of the eyes. Vision following COVID-19 infection or vaccination should be considered correlative in a clinical setting.

CONTRIBUTION OF THE AUTHORS

Bianca Luiza Valduga Guareschi: contributed to the review of articles, submission to the Ethics Committee, data collection, description of case reports and drafting of the article; Amanda Geara: contributed to the literature review, drafting of the article and data collection; Heloísa Helena Abil Russ: contributed to the literature review, data collection and critical review of the written work; João Guilherme Oliveira de Moraes: contributed to the literature review, data collection and critical review of the written work; Mario Teruo Sato: contributed to the literature review, data collection and critical review of the written work; Bret A Moore: contributed to the literature review and critical review of the written work in the English language; Fabiano Montiani Ferreira: contri

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