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Artículo original

Seguridad de la vacunación COVID-19 en una muestra de pacientes brasileños con lupus eritematoso sistémico

Safety of COVID-19 vaccination in a sample of Brazilian patients with systemic lupus erythematosus patients

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Palabras clave: lupus eritematoso sistémico; COVID-19; vacunas; seguridad.

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RESUMEN

Objetivos: estudiar los efectos secundarios y el riesgo de exacerbación de la enfermedad después de la vacunación COVID-19 en una muestra de pacientes con lupus eritematoso sistémico (LES).

Materiales y métodos: estudio retrospectivo que investigó 101 pacientes con LES. Se determinó la actividad de la enfermedad mediante el *Systemic Lupus Erythematosus Disease Activity Index* (SLEDAI) antes y después de dos dosis de la vacuna contra el SARS-COv-2. Se registraron los efectos secundarios después de la vacunación.

Resultados: los pacientes que recibieron dos dosis de la misma vacuna fueron el 10,3% para CoronaVAc, el 42,2% para Pfizer y el 47,3% para AstraZeneca. Se detectaron efectos secundarios en el 76,2% y la mayoría fue leve/moderado. Los más frecuentes fueron: dolor local (62,3%), cefalea (36,6%) y fatiga (34,6%). El cambio en la mediana del SLEDAI antes de la primera dosis y después de la segunda no fue estadísticamente significativo (p=0,68). Solo el 4,1% de los individuos aumentó el SLEDAI ≥ de 3 puntos.

Conclusiones: la vacunación contra la COVID-19 fue bien tolerada y segura en pacientes con LES.

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Key words: *systemic lupus erythematosus; COVID-19; vaccines; safety.*

ABSTRACT

Objectives: *to study the side effects and the risk of disease flare after COVID-19 vaccination in Brazilian patients with Systemic Lupus erythematosus (SLE).*

Materials and methods: *this retrospective study investigated a sample of 101 SLE patients for disease activity through the SLE disease activity index (SLEDAI) prior to and after two vaccine doses against SARS-COv-2. Side effects after vaccination were recorded.*

Results: *in this sample, patients receiving two doses of the same vaccine were 10.3% for CoronaVAc; 42.2% for Pfizer, and 47.3% for Astra-Zeneca. Side effects were detected in 76.2% of them, and most of them were mild and moderate; the most common were local pain (62.3%), headache (36.6%), and fatigue (34.6%). The SLEDAI prior to the first dose and after the second dose did not change significantly (p=0.68). Only 4.1% of individuals had increased in SLEDAI ≥than 3 points.*

Conclusions: *vaccination against COVID-19 was well tolerated and safe in SLE patients.*

INTRODUCTION

Systemic lupus erythematosus (SLE) is an autoimmune disease in which autoantibodies against self-structures are synthesized[1]. The etiopathogenesis of this disease is multifactorial, and infections are supposed to play an important role in this context, as microorganisms may stimulate the immune system. Cross-reaction of microorganisms' structures with self-antigens or molecular mimicry is one of the possible explanations[2-4]. Moreover, amplified B cell activation results in expanded immune response and increased interferon levels. This cytokine has a crucial role in adequate pathogen response and is important in SLE pathophysiology. Therefore, several infections, mainly viral, have been described just before SLE flares[5]. Herpes zoster infection[6], cytomegalovirus[7], and parvovirus B19[8] are some of them. Recently, the infection by the COVID-19 virus has also been implicated in this setting[6,9].

On the other hand, vaccination may offer similar antigens as the original infection, and the risk of SLE reactivation post-vaccination is uncertain[10,11]. Nevertheless, vaccination is vital for this group of patients as they are immunosuppressed[12]. Infections are one of the main causes of death in SLE[13]. Therefore, studies in vaccine safety are of fundamental importance in immune-mediated diseases.

Our objective was to estimate the side effects and the risk of disease flare after COVID-19 vaccination in Brazilian patients with SLE.

MATERIALS AND METHODS

This is a retrospective study performed in a single rheumatology unit that cares for patients from the public health system. A convenience sample included all SLE patients who came for regular consultation from March to September 2021. Patients were invited to participate according to appointment order, which included observing inclusion and exclusion criteria and the patient's willingness to participate in the study.

To be included, patients should have fulfilled at least 10 points in the 2019 SLE Classification Criteria from ACR/EULAR (American College of Rheumatology/ European League Against Rheumatism). They should also have received two COVID-19 vaccine doses and be older than 18 years of age. Pregnant patients and those unable to understand the consent form were excluded.

We collected epidemiological and clinical data: sex, age, auto-declared ethnic background, comorbidities, and used medication. Data on disease activity in the last consultation prior to the first vaccine dose and in the first consultation after the second vaccine dose were registered using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). SLEDAI is an instrument that scores 24 clinical and laboratory manifestations; it goes from zero to 105 with high values, which means high disease activity. SLE was considered inactive when SLEDAI is < 4[14,15]. An increase of 3 points in the SLEDAI score was considered as a disease flare[16]. The study of possible changes in the SLEDAI was done only in patients receiving two doses of the same type of vaccine.

A questionnaire with "Yes/No" answers on the following vaccination side effects was done: local pain, myalgias, fatigue, headache, arthralgias, skin rashes, and nausea/diarrhea. If the answer was "Yes," the patients were invited to quantify the symptoms as mild, moderate, or severe. Side effects not listed previously were reported as "others" in an open question.

The following questions were developed regarding the patient's perception of vaccination: a) have you been afraid of receiving the COVID-19 vaccine?; b) according to your perception, do you believe that your disease (SLE) became more active after vaccination?

In statistical analysis, categorical data were expressed in numbers and percentages; numerical data in mean and SD (standard deviation) or median and IQR (interquartile range). Comparison of categorical variables (number of patients with vaccine side effects) was done by Fisher and chi-squared tests, and comparison of numerical variables (SLEDAI) was done through Wilcoxon matched-pairs signed rank test using GraphPad Prism version 8.0.0 for Windows, GraphPad Software, San Diego, California USA, www.graphpad.com". $p<0.05$ was considered significant.

This study was approved by the local committee of ethics in research under protocol number 5.123.370 and all participants signed an informed consent.

RESULTS

One hundred and one SLE patients were included. Table 1 shows the epidemiological and clinical data, treatments, and the presence of comorbidities.

Side effects post-vaccination were present in 77/101 (76.2%) of the sample, and they are

listed in Table 2. Most of them were mild or moderate. Local pain was the most common complaint. None of the interviewed patients had severe side effects, such as severe allergies, anaphylaxis, or thrombosis, and none required hospitalization. The comparison of side effects among the different vaccine types showed no differences (all non-statistically significant).

About 10/101 (9.9%) patients believed that the SLE became more active after vaccination; 35/101 (34.6%) patients declared being afraid of receiving the first dose of the vaccine. Of those who believed that the SLE became active after the use of the vaccine, only one patient had a change in SLEDAI ≥3.

The median period between the last SLEDAI measurement prior to vaccination and the first vaccine shot was 30 days (IQR=16-51), and the median period between the second shot and the second SLEDAI measurement was 31 days (IQR=30-60).

SLEDAI prior to vaccination ranged from 0-28, with a median value of 0 (IQR=0-2). SLEDAI after vaccination ranged from 0 - 17, with a median of 0 (IQR=0-0); p=0.68. In 4/97 (4.1%), the SLEDAI increased more than 3 points from baseline, with proteinuria in three patients and arthritis in two. Two of them had active disease when they received the first vaccine dose.

When comparing SLEDAI values prior and after vaccination according to vaccine type, no differences were found for Astra Zeneca vaccine (p=0.85), and neither for the CoronaVac (p=0.50). However, a decrease in those receiving the Pfizer vaccine was observed (SLEDAI before vaccination with a median value of 0; IQR=0-2; after vaccination with a median value of 0; IQR=0-0; p=0.04).

Table 1: Characteristics of the lupus patients.	
Female, n (%)	92 (91.0)
Age (years), mean (SD)	42.9 ± 14.4
Ethnic background	
Afro-descendants, n (%)	21 (20.7)
Caucasians, n (%)	80 (79.2)
Presence of glomerulonephritis, n (%)	48 (47.5)
Comorbities	
Presence of secondary antiphospholipid syndrome, n (%)	14 (13.8)
Secondary Sjögren, n (%)	11 (10.0)
Fibromyalgia, n (%)	17 (16.8)
Neoplasy, n (%)	02 (1.9)
Asthma or bronchitis, n (%)	03 (2.9)
Arterial hypertension, n (%)	40 (39.6)
Hypothyroidism, n (%)	25 (24.7)
Dyslipidemia, n (%)	15 (14.8)
Diabetes mellitus, n (%)	9 (8.9)
Coronary artery disease, n (%)	2 (1.9)
Treatment	
Antimalarial, n (%)	88 (87.1)
Mofetil mycophenolate, n (%)	41 (40.5)
Glucococorticoid, n (%)	29 (28.7)
Methotrexate, n (%)	10 (9.9)
Azathioprine, n (%)	9 (8.9)
Rituximab, n (%)	7 (6.9)
Tacrolimus, n (%)	5 (4.9)
Talidomide, n (%)	4 (3.9)
Cyclophosphamide, n (%)	2 (1.9)
Belimumab, n (%)	1 (0.9)
Used vaccines (*) n=97	
CoronaVac, n (%)	10 (10.3)
Pfizer, n (%)	41 (42.2)
AstraZeneca, n (%)	46 (47.4)

(*) Only those receiving the same vaccine in the first and second dose were considered.
N: number, SD: standard deviation.

Table 2: Side effects post COVID-19 vaccination in patients with systemic lupus erythematosus (n=101).

	n (%)	n (%)	
Local pain	63 (62.3)	Mild	43 (42.5)
		Moderate	16 (15.8)
		Severe	4 (3.9)
Headache	37 (36.6)	Mild	22 (21.7)
		Moderate	9 (8.9)
		Severe	6 (5.9)
Fatigue	35 (34.6%)	Mild	21 (20.7)
		Moderate	10 (9.9)
		Severe	4 (3.9)
Myalgias	27 (26.7)	Mild	15 (14.8)
		Moderate	9 (8.9)
		Severe	3 (2.9)
Arthralgias	11 (10.8)	Mild	6 (5.9)
		Moderate	2 (1.9)
		Severe	3 (2.9)
Nauseas/diarrhea	6 (5.9)	Mild	2 (1.9)
		Moderate	2 (1.9)
		Severe	2 (1.9)

N: number.

DISCUSSION

The present results are reassuring concerning the use of COVID-19 vaccines in SLE patients. No important changes in SLEDAI were observed, and the immediate side effects were comparable to those experienced by the general population. In the current sample, the side effects were similar among the three vaccine types.

Concerns about vaccine safety are common in the rheumatological community. Live vaccines are not indicated in immunocompromised patients such as those with SLE, taking into account the risk of uncontrolled viral replication[18]. Also, the medical literature has documented the development of de novo autoimmune disease or flares of existing autoimmune disease after vaccine administration[18,19]. Immunization with the hepatitis B virus (HBV) vaccine in SLE animal models has been shown to accelerate renal disease, and the animals' kidney histology showed deposition of HBV antigen[20]. In humans, a case series of SLE developing after they received HBV vaccination has been described, and Agmon-Levin et al. observed that they are clinically similar to drug-induced lupus[21]. Nevertheless, a prospective study in a cohort of 28 SLE patients showed that this vaccine was safe, well-tolerated, and efficacious[22].

The human papillomavirus (HPV) vaccine has also been implicated in new-onset lupus. One case-control study using a database from the vaccine adverse event reporting system (VAERS) from 2006 to 2012 reported an OR of 7.6 (95%CI=3.3-19.3) for the development of SLE following the administration of quadrivalent HPV vaccine[23]. On the other hand, another study involving 113 specialized centers could not prove this association[24]. As can be seen, controversies about the possibility of lupus appearing after vaccination are common. Regarding COVID-19 vaccination, the toll-like receptor used as an adjuvant has the potential to induce SLE flares, upregulating the type I interferon pathway[25]. Several autoimmune phenomena have been described following vaccination, such as ANCA-associated vasculitis[26], myositis[27], autoimmune hemolytic anemia[28], and thrombocytopenic purpura[29], among others. However, the existing data is mostly based on case descriptions. The emergence of autoantibodies after COVID-19 infections has better documentation: anti 52 kDa SSA-Ro/TRIM21[30], anti-cardiolipins[31], and rheumatoid factors[32] are some of them, but the development of autoantibodies after COVID-19 vaccinations is less studied.

COVID-19 vaccination adverse events in SLE patients in the COVAD study[33], which included 583 individuals among others with autoimmu-

ne diseases, observed minor adverse events in 83% of them, major in 2.6%, and hospitalizations in 0.2% of the sample. This study was done through an internet questionnaire; therefore, details about the mentioned side effects were not available. Moreover, this survey discussed problems occurring immediately (7 days) after vaccination, and the SLEDAI score was not followed[17]. Another internet survey study aiming to see side effects, including SLE flares, reported that 21/696 (3%) informed having a medically confirmed flare of the disease after a median of 3 days after vaccination[33].

Moyon et al.[34], studying 126 French patients with active and inactive SLE, observed that the BNT162b2 (Pfizer) vaccine was safe, well tolerated, and did not cause any changes in the evaluated activity indexes measured by SLEDAI and BILAG (or British Isles Lupus Assessment Group), corroborating our findings. Furthermore, another report[35], including 90 American SLE patients, showed that the pre and postvaccination SLEDAI scores (measured in 55 of them) were similar; flares occurred in 11.4% of patients, and in only one, it was considered severe (with arthritis requiring methotrexate treatment). Mock et al.[36] compared the number of flares in vaccinated and unvaccinated SLE patients and found no significant differences. SLE is a disease with periods of remitting and recurring activity. Therefore, adjudicating a disease flare to the vaccine is difficult. This cyclic pattern of the disease activity could explain the interesting finding of decreased SLEDAI values observed presently in Pfizer vaccine users.

About one-third of our sample was afraid of receiving the COVID-19 vaccination. COVID-19 vaccines were rushed into testing, bypassing some animal experimentations due to the severity of the infection outbreak[37]; it is comprehensible that they raised apprehension on efficacy and safety and generated indecision regarding their use. Nevertheless, it must be considered that SLE patients are a high-risk population concerning outcomes associated with SARS–CoV–2 infection not only due to immunosuppression caused by the disease and treatment but also because they have a high number of comorbidities such as hypertension (present in 40% of the present study sample) that is a predictor of hospitalization[38]. Thus, knowing that COVID-19 vaccination is safe should be reassuring to these populations and to those involved in their care.

This series is limited by the low number of patients and its retrospective design. Moreover, vaccination efficiency was not studied. It is important to mention that Tan et al.[39] reviewed the data from 32 studies comprising 8269 individuals with SLE showing that post-vaccine COVID-19 severe flares, and adverse events were infrequent. Our cohort has the benefit of showing the local data: that COVID-19 vaccine is safe for local lupus patients in a real-life scenario.

In conclusion, the present results indicate that COVID-19 vaccines are safe and well-tolerable in SLE patients.

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