Psychological and quality of life effects of vaccination against COVID-19 in patients with systemic autoimmune diseases

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Abstract

To verify the psychological and quality of life benefits of vaccination against COVID-19 in patients with systemic autoimmune diseases. In this study, levels of psychological stress, psychopathological symptoms, quality of life, and satisfaction with life were compared in patients with systemic autoimmune diseases vaccinated against COVID-19 (n = 132) versus unvaccinated patients (n = 254). To this end, we used the *Perceived Stress Scale* (PSS), *Symptom Checklist-90-Revised* (SCL-90-R), *EUROQoL-5Q health questionnaire*, and *Satisfaction with Life Scale* (SWLS), respectively. Statistically significant differences were found with better scores in the vaccinated group in the following quality of life dimensions: mobility ($p \le 0.010$), domestic activities ($p \le 0.004$), pain/discomfort ($p \le 0.001$), and anxiety/depression ($p \le 0.005$). The scores were also significantly higher in the vaccinated group for the total values of quality of life ($p \le 0.001$), health status self-assessment on the EUROQoL-5Q ($p \le 0.043$), and satisfaction with life ($p \le 0.015$). In addition, the unvaccinated group presented higher scores with clinically pathological levels in depression and psychoticism for somatizations ($p \le 0.006$), depression ($p \le 0.015$), anxiety ($p \le 0.003$), and phobic anxiety ($p \le 0.001$). Finally, participants vaccinated with the complete regimen showed better levels of psychological well-being than those who were not vaccinated or those that had not completed the vaccination regimen. Our results reflect and confirm the positive effects reported elsewhere of the COVID-19 vaccine in autoimmune patients with systemic diseases, both in terms of quality and satisfaction with life as well as psychopathological symptoms and perceived stress. These benefits increased as the patients completed their vaccination schedule.

Keywords

Autoimmune diseases, covid-19, psychological status, quality of life, vaccine

Introduction

At the end of 2019, the first cases of a new disease caused by SARS-CoV-2, COVID-19, were detected in China. Soon after, the outbreak was declared a pandemic and an international public health emergency by the World Health Organization (WHO). Obtaining an effective vaccine became a global health goal and, surprisingly, a reality in just 10 months, when the usual timeframe for developing vaccines is 10–15 years.¹ Factors such as knowledge of the structure of the spike protein and its importance in the induction of neutralizing antibodies (based on studies of previous outbreaks of other coronaviruses), the ability to carry out multiple phases of clinical trials in parallel, and advancement of complementary technologies, all contributed to shortening the process.¹⁻³ Nonetheless, this speed also meant that vaccine trials focused primarily on the healthy population and not on all age ranges. Thus, at the beginning of the vaccination process, starting worldwide at the end of 2020, populations such as children, pregnant women, or patients with autoimmune diseases, among others, were not

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included in the initial vaccination plans. However, given the evolution of the pandemic and, once the efficacy of these vaccines had been proven, encouraging vaccination against COVID-19 became essential for all possible population groups, regardless of their characteristics or age.

A study on COVID-19 vaccination in patients with immune-mediated inflammatory diseases from early 2021^4 concluded that its safety and efficacy in this population was like that of other vaccines widely recommended for this patient group. Recently, these same authors have confirmed that the BNTb262 mRNA vaccine has an acceptable safety profile and is immunogenic in most of these patients.⁵ Likewise, numerous studies have shown that vaccines are effective and safe in patients with autoimmune diseases, including those taking immunosuppressive drugs.¹ Given all the above, the American College of Rheumatology and the Center for Disease Control recommend the administration of COVID-19 mRNA vaccines to patients with autoimmune diseases, regardless of the level of disease activity and/or severity, and whether they are taking immunosuppressive drugs, provided they have no other contraindications.^{1,6,7}

Apart from the physical effects of SARS-CoV-2 infection, patients with autoimmune diseases also present notable psychological consequences in association with the pandemic. For example, a study conducted with people with systemic lupus erythematosus showed that they presented symptoms such as fear of becoming infected, generalized anxiety, loneliness, or frustration related to a reduction in subjective psychological wellbeing and quality of life.⁸ Importantly, in patients with autoimmune diseases, these variables constitute risk factors for exacerbation of the disease that can further affect their physical and psychological well-being. In addition, anxiety related to COVID-19 and fears associated with one's own health or that of loved ones were directly related to a high acceptance of receiving the COVID-19 vaccine to reduce the probability of the negative consequences of contracting the disease.¹⁰ Therefore, these variables would facilitate the vaccination process in people with an autoimmune disease.

Given all the above, the objective of this current study was to verify the psychological benefits of vaccination against COVID-19 in patients with systemic autoimmune diseases. First, we verified whether people with autoimmune diseases who were vaccinated presented less psychological stress, fewer psychopathological symptoms, and a better quality of life compared to those who were not vaccinated. We subsequently studied whether these variables were modulated depending on administration of the complete vaccine schedule, which consisted of two doses at the time of the study.

Patients and methods

Patients

This study involved 386 patients with systemic autoimmune diseases such as lupus, antiphospholipid syndrome, vasculitis, and sarcoidosis, among others. The participants were divided into two groups: the vaccinated group comprising 124 women and eight men, and the unvaccinated group which consisted of 236 women and 18 men.

Procedure

Both groups completed an online form (via the Google Forms tool) consisting of the complete evaluation battery. The participants were contacted in May 2021 through social networks that bring together patients with different systemic autoimmune diseases treated in health centers throughout Spain. Those interested in participating in the study filled out the form available online during the month of June 2021. The inclusion criteria were being of legal age, a diagnosis of a systemic autoimmune disease, and knowing how to read/write in Spanish. All the participants were provided with the patient information sheet, informed consent declaration, and revocation document. The study was approved by the Ethics Committee at the University of Jaén (JUN.21/3.OTR) and was conducted in accordance with the principles of the Declaration of Helsinki¹¹ and the Directive on Good Clinical Practices of the European Union (Directive 2005/28/EC).

Data collection

Sociodemographic, clinical, and vaccination-related variables. These variables were collected through a semistructured online interview designed specifically for this study that includes the main sociodemographic variables, as well as those related to systemic autoimmune disease, SARS-CoV-2, and COVID-19 vaccination. In addition to, the unvaccinated group was asked for the intention to be vaccinated with three response options: yes, no or depends on the vaccine laboratory.

The *Perceived Stress Scale* (PSS).¹² The Spanish version of the PSS (the EEP in its Spanish acronym) first published by Remor and Carrobles¹³ was used. This is a self-reported metric that assesses the level of perceived stress and the degree to which people find their life to be unpredictable, uncontrollable, or overloaded. It consists of 14 items with five response options, with the highest score corresponding to the highest level of perceived stress. The EEP (which also contains 14 items) demonstrated adequate reliability (an internal consistency of 0.81 and test-retest value of 0.73), concurrent validity, and sensitivity levels.¹⁴

The Symptom Checklist-90-Revised (SCL-90-R).¹⁵ The SCL-90-R is used to inventory psychological distress and psychopathological symptoms. It is a selfreported scale comprising 90 items with five response alternatives (0-4). Surveyees should answer based on how they felt in the 7 days prior, including the day they complete the inventory. The SCL-90-R evaluates nine primary dimensions (somatizations, obsessions and compulsions, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism), and three global indices of psychological distress (the global severity index [GSI], total positive symptoms [PS], and positive symptom distress index [PSDI]). For the statistical analyses we calculated the percentile of the results of each participant in this inventory.

The EUROQoL-5Q health questionnaire.¹⁶ The EUROQoL-5Q measures health-related quality of life (HROoL) both in the general population and in groups of patients with different pathologies. The participant is asked to assess their state of health, first in terms of the severity levels for five health dimensions (mobility, personal care, daily activities, pain/discomfort, and anxiety/depression), with each of these dimensions having three severity levels (no problems, some problems, or moderate and serious problems). The higher the score in each of these subscales, the better the participant's health status and quality of life. Next the participants respond to a more general health status selfassessment using a visual analogue scale from 0 (the worst state of health imaginable) to 100 (the best state of health imaginable).

The *Satisfaction With Life Scale* (SWLS).^{17,18} The SWLS comprises five items that evaluate the participant's global satisfaction with life based on the degree of agreement from 1 (strongly disagree) to 5 (strongly agree) on the following factors: (1) if their lifestyle is similar to the one they had always dreamed of having; (2) if their living conditions are excellent; (3) participant satisfaction with their life; (4) if they have obtained the important things in life; and finally, (5) if they could live again, whether they would change anything.

Statistical analysis

Statistical analysis of the results was carried out using SPSS[®] software (version 26.0; IBM Corp., Armonk, NY, USA). First, the sample of patients with autoimmune diseases was divided into vaccinated (V) and unvaccinated (UV) groups. Next, Student *t* -tests for the continuous variables and Chi-squared tests (χ^2) for the categorical variables were conducted to check whether there were significant differences between these groups in terms of the main sociodemographic

variables. Variables for which significant differences were found were included as covariates in the subsequent analysis.

Secondly, a MANCOVA analysis was performed to check for differences in the variables of stress, psychopathological symptoms, life satisfaction, and quality of life between the V and UV groups, using 'vaccine' as the between-group variable with two levels (vaccinated vs unvaccinated), and including age as a covariate. The scores obtained in each of the questionnaires were included as dependent variables. Finally, MANCOVAs were also performed to check whether there were statistically significant differences between the patients with autoimmune diseases with different levels of vaccination (a full dose schedule vs having received one or no doses), using 'dose' as the between-group variable, the scores obtained in the psychological variables as the dependent variables, and age as a covariate.

Results

Sample description. The sociodemographic and clinical data of the participants are shown in Table 1. The results showed that the age and education levels were significantly higher in the V group and so these factors were included as covariates in the subsequent analyses. No statistically significant differences were found for any of the other variables measured. On the other hand, in the variable of intention to be vaccinated, the 2% answered that they would not be vaccinated, the 86.2% would be vaccinated, and the 11.8% depends on the vaccine laboratory.

Perceived stress, psychopathological symptoms, quality of life, and life satisfaction in vaccinated versus unvaccinated patients with systemic autoimmune disease. As shown in Table 2, on the one hand, the results showed that the scores for the dimensions of mobility ($p \le 0.010$), domestic activities ($p \le 0.004$), pain/discomfort ($p \le 0.001$), and anxiety/depression ($p \le 0.005$) related to quality of life were significantly lower in the UV group compared to the V group. On the other hand, the overall quality of life ($p \le$ 0.001), self-assessed EUROQoL-Q5 state of health ($p \le$ 0.043), and satisfaction with life ($p \le 0.015$) scores were better in the V group.

Finally, the scores for the SCL-90-R scales for somatizations ($p \le 0.006$), depression ($p \le 0.015$), anxiety ($p \le 0.003$), and phobic anxiety ($p \le 0.001$) were significantly higher in the UV group compared to the V group. In addition, the UV group presented scores with clinically pathological levels for depression and psychoticism (percentile exceeding 70). Both the V and UV groups presented pathological levels on the somatization scale. No statistically significant differences were found between the two groups for any of the other variables.

		Vaccinated n = 132	Unvaccinated n = 254	Þ
Sociodemographic variables				
Age (Years), (SD)		50.55(12.33)	43.24(9.82)	0.001*
Education level, n(%)	Without studies/basic studies	_ ` `	. ,	0.021*
	Primary studies	8(6.1%)	28(11%)	
	Secondary studies	39(29.5%)	90(35.4%)	
	University studies	85(64.4%)	136(53.5%)	
Clinical variables, n(%)				
Type of systemic autoimmune disease				0.762
Lupus	_	50(31.65%)	108(68.35%)	
Antiphospholipid syndrome	—	10(43.48%)	13(56.52%)	
Sjogren's syndrome	_	9(75%)	3(25%)	_
Scleroderma	—	8(61.54%)	5(38.48%)	_
Sarcoidosis	—	4(18.18%)	18(81.82%)	
Vasculitis	—	7(26%)	20(74%)	
Rheumatoid arthritis	_	4(40%)	6(60%)	
Others (miositis, spondyloarthropathies, etc.)	_	40(33.05%)	81(66.94%)	_
Have you been diagnosed with any other illness?	Yes	84(63.64%)	146(57.48%)	0.242
	No	48(36.36%)	108(42.52%)	
Have you been diagnosed with any psychological disorder?	Yes	40(30.30%)	95(37.40%)	0.165
	No	92(69.70%)	159(62.60%)	
Has COVID-19 passed?	Yes	3(2.27%)	33(13%)	0.001*
•	No	129(97.73%)	221 (87%)	_

Table I. Descriptive and differential analysis of the groups in the sociodemographic and clinical variables.

 Table 2. Differences between groups in stress and psychopathological symptoms.

	Vaccinated (n=132) (SD)	Unvaccinated (n=254) (SD)	t	Þ
Psychological stress				
Perceived stress scale	28.67(5.36)	30.02(5.37)	2.416	0.121
Quality of life				
EUROQOLI_MOBILITY	1.72(0.45)	l.65(0.49)	6.741	0.010*
EUROQOL2_PERSONAL CARE	1.85(0.37)	1.80(0.42)	3.020	0.083
EUROQOL3_DOMESTIC ACTIVITIES	1.49(0.56)	1.35(0.55)	8.3585	0.004*
EUROQOL4_PAIN/DISCOMFORT	1.02(0.56)	0.87(0.59)	11.791	0.001*
EUROQOL5_ ANXIETY/DEPRESSION	1.42(0.59)	1.24(0.68)	7.822	0.005*
EUROQOL_TOTAL	7.50(1.81)	6.89(1.97)	14.946	0.001*
EUROQOL_HEALTH STATUS self-assessment	56.30(22.02)	53(25.10)	4.112	0.043*
Satisfaction with life				
Satisfaction with life scale	15.08(4.24)	13.86(4.48)	6.004	0.015*
SCL-90-R				
Somatizations	75.06(23.52)	80.62(21.63)	7.649	0.006*
Obsessions and compulsions	54.62(42.70)	62.72(41.02)	3.157	0.076
Interpersonal sensitivity	63.73(28.41)	67.10(29.87)	0.158	0.692
Depression	62.66(29.59)	71.10(27.10)	5.914	0.015*
Anxiety	60.24(29.78)	69.63(27.17)	9.097	0.003*
Hostility	44.53(35.31)	51.88(34.51)	1.145	0.285
Phobic anxiety	43.12(37.03)	58.75(34.31)	17.332	0.001*
Paranoid ideation	54.53(31.94)	54.68(35.12)	0.113	0.737
Psychoticism	68.17(28.18)	71.03(28.61)	2.989	0.085



Figure 1. Mean scores in perceived stress and psychopathological symptoms (SCL-90-R) that showed statistically significant differences between groups according to administered doses.



Figure 2. Dimensions of the EUROQOL-5Q and Satisfaction with Life Scale (SWLS) that showed significant differences between groups: unvaccinated group, one-dose vaccinated group and two-dose vaccinated group.

As shown in Figures 1 and 2, there were significant differences for stress, psychopathologies, and quality of life in our study sample when these patients were divided into three groups according to the number of COVID-19 vaccine doses administered: no doses, one dose, or two doses (full vaccination schedule). Figure 1 shows the scores for perceived stress and the somatization, anxiety, and phobic

anxiety dimensions of the SLC-90-R. Post hoc analyzes showed significant differences between the unvaccinated group and the fully vaccinated group in terms of perceived stress ($p \le 0.011$), somatizations ($p \le 0.016$), and anxiety ($p \le 0.001$). Furthermore, there were differences between both the unvaccinated group and the one-dose group ($p \le 0.028$) and the unvaccinated group and the two-dose group $(p \le 0.001)$ for phobic anxiety, with all these scores being higher in the unvaccinated group.

Figure 2 shows the scores in the dimensions of domestic activities, pain/discomfort, and total quality of life dimensions of the EUROQoL-5Q health questionnaire as well as satisfaction with life, some of which showed statistically significant differences. Post hoc analyzes showed differences in household activities both between the two-dose vaccinated group and the unvaccinated group ($p \le 0.002$) and the two-dose group versus the one-dose group (p <0.041). In the pain/discomfort ($p \le 0.03$) and total quality of life ($p \le 0.006$) dimensions, the differences were between the unvaccinated group and the fully vaccinated group. In turn, quality of life scores were lower in the unvaccinated group. Regarding satisfaction with life, there were significant differences between the unvaccinated group and the fully vaccinated group ($p \le 0.001$) and the one-dose and two-dose groups ($p \le 0.016$) where the fully vaccinated group showed greater satisfaction with life scores.

Discussion

The aim of this study was to compare the psychological state and quality of life of patients with systemic autoimmune diseases vaccinated for COVID-19 versus their unvaccinated counterparts. In addition, the psychological effects of COVID-19 vaccination were also compared more specifically considering the number of administered doses of the vaccine. Therefore, this is one of the first studies to evaluate the psychological consequences of being vaccinated against COVID-19 in patients with systemic autoimmune disease. This work allows us to better understand the possible psychological consequences of vaccination against this contagious and serious disease in people with a systemic autoimmune disease.

Our results showed that, compared to the V group, the UV group of patients presented worse scores for several areas of their psychological state, as well as a poorer perception of their physical health. Specifically, the UV group had a worse overall quality of life with greater difficulties in mobility, performing housework, more pain/discomfort, and greater anxiety/depression. All of this was confirmed along with lower participant self-assessment scores for their general health status and life satisfaction levels. In addition, regarding psychopathological symptoms, the UV patient group obtained higher scores for somatization, depression, anxiety, and phobic anxiety, showing clinical pathological scores for depression and psychoticism. Therefore, vaccination in these patients can be beneficial to cushion the possible fears generated by COVID-19.

Along these lines, a recent study conducted in the general population of the USA found that having been vaccinated against COVID-19 was associated with a decrease in psychological distress and in the perceived risks of infection, hospitalization, and death.¹⁹ This effect was shown even though vaccinated versus unvaccinated participants shared the same levels of psychological distress and perceived risks before vaccination, with these trends only significantly diverging after vaccination. These findings are in line with the results of the present study, in which patients with systemic autoimmune disease who were unvaccinated maintained higher levels of psychological distress and psychopathology compared to their vaccinated counterparts. These data are of foremost importance for the promotion of vaccination among this population, which is at risk because of their altered immune systems.

Also of note, both groups presented clinically pathological scores for somatizations, which was expected given that patients with systemic autoimmune diseases experience many chronic symptoms. However, there were significant differences between both groups in this dimension, with the group of unvaccinated patients presenting higher levels of somatization. When comparing the quality of life and the psychological state according to the number of doses, we were able to verify the positive effect of vaccination in our cohort. The results of this comparison showed how the group of patients with systemic autoimmune diseases vaccinated with two doses presented lower perceived psychological stress as well as a higher quality of life both in general and more specifically in terms of domestic activities and pain/discomfort.

The improvement in the self-perceived ability to complete domestic activities occurred after receiving the first dose, and further improved when the patients received the second dose. That is, as the vaccination schedule was completed, the level of domestic activity for this dimension improved. Something similar was observed when analyzing life satisfaction, with better scores being obtained both in the group vaccinated with two doses compared to the unvaccinated group, and in the fully vaccinated group compared to the group that had received a single dose. The comparison according to the number of doses also showed differences in the dimensions of somatization, anxiety, and phobic anxiety between the unvaccinated and fully vaccinated patients. For phobic anxiety, differences were also observed between the single-dose and two-dose groups. As with the other dimensions, scores in the two-dose vaccinated group were better than in the other two groups.

These results reflect and confirm the positive effects the COVID-19 vaccine has on autoimmune patients with systemic diseases, both in terms of life quality and satisfaction and in psychopathological symptoms. The higher scores in variables such as perceived stress, somatization, anxiety, depression, and phobic anxiety in the UV group may be because of factors such as fear of contagion and decreased interpersonal contacts. The fear of contagion and the reduction of interpersonal relationships can facilitate an

increase in anxiety and depression, as well as the level of perceived stress generated by the pandemic, the feeling of lack of protection, generalized anxiety, and/or loneliness. Among others, these psychological consequences of COVID-19 have been related to a reduction in subjective psychological well-being and quality of life in patients with systemic lupus erythematosus⁸ and have also been confirmed in the results of this present study.

In addition, these symptoms are stressful and therefore, themselves represent risk factors that can also be related to a possible exacerbation of the symptoms of the autoimmune disease (as mediated by deregulation of the hypothalamic pituitary-adrenal axis) and can affect the physical, cognitive and psychological well-being of these patients.9,20,21 This, in turn, is consistent with our results showing worse general self-assessment scores for health status in the unvaccinated group compared to the vaccinated group and worse selfperceived physical health in dimensions including mobility, housework, or discomfort/pain together with higher levels of somatization and lower satisfaction with life, in addition to the fact that the group of vaccinated patients were older. These differences were accentuated as the vaccination schedule was completed and the positive effects of the vaccine became noticeable, not only between the UV versus the V group, but also between the unvaccinated, one-dose, and fully vaccinated groups. Thus, as the vaccination schedule was completed, the patients showed a better overall quality of life, psychological state, and selfperceived physical status.

Previous studies^{4–7} have shown that vaccination against COVID-19 was medically safe and effective in patients with autoimmune diseases, regardless of the level of disease activity and/or severity, or immunosuppressive drugs used, as long as they presented no contraindications for the vaccine. Our study further shows that these positive effects have serious psychological implications related only to the mere fact of having received the vaccine, as an additional benefit to COVID-19 vaccination.

Finally, we must consider the limitations of this current study. First, there were differences in the sample size of the UV and U groups; a more even number of participants would have allowed us to determine if these differences would have been accentuated or diminished in the variables studied. However, the staggered vaccination process according to age made it difficult to create groups that were matched in terms of number. Moreover, it would have been interesting to evaluate the quality of life and psychological status in the same group of people before and after vaccination to verify the differences between the U and UV groups and the positive effects of the vaccine identified in this work. However, the speed of the vaccination process itself complicated the application of this methodology in this present study. Finally, with the lack of pre vaccination data we do not know if UV group would have had worse baseline stress/psychological levels as compared to V group. Nevertheless, only the two per cent of the UV group did not intend to be vaccinated, thus, to decline vaccination variable would not be an influential variable in the baseline psychological and stress symptoms.

In conclusion, this present study showed additional positive effects of vaccination against COVID-19 in patients with systemic autoimmune diseases, both in terms of quality of life and in stress and psychopathologies. These results have important clinical and research implications given that they indicate that future research should be directed towards studying factors that promote and favor the decision to be vaccinated and reducing doubts associated with the vaccine. In addition, this study provides more information on the benefits of COVID-19 vaccination, both in medical and psychological terms.

Declaration of Conflicting Interests

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