Post-Covid 19 Vaccination in Ankylosing Spondylitis and Psoriatic Arthritis Patients

Original Article

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ABSTRACT

Background: The risk of contracting COVID 19 in patients suffering of ankylosing spondylitis (AS) and psoriatic arthritis (PsA) diseases has been a focus of ongoing studies. Because of the lack of safety and efficacy data for COVID 19 vaccine in patients with rheumatic diseases and the special interests for the use of immunomodulators , there may be important attitudes differences toward COVID 19 vaccination between systemic rheumatic diseases patients and the general population.

Objective: To study the response of COVID 19 vaccines in patients with ankylosing spondylitis and psoriatic arthritis regarding effectiveness and side effects.

Subjects and Methods: A case control study including a group of 50 patients with ankylosing spondylitis and psoriatic arthritis and a group of 50 age and sex matched healthy controls. Type of vaccine and side effects were recorded for all participants 6 weeks after vaccination. Disease activity was measured using (ASDAS) Ankylosing spondylitis disease activity score and (DAPSA) Disease Activity in Psoriatic Arthritis Score. Measuring COVID 19 serum IgG antibody was performed for all participants.

Results: COVID-19 IgG serum levels post vaccination were significantly lower in the group of cases 88.2 mg/dL (78 – 90.1) than the control group. 93.8 mg/dL (92 – 95), P< 0.0001. There was no significant difference between cases and control group regarding vaccine side effects (P= 0.16) or response (P= 0.16). COVID-19 IgG antibody levels significantly negatively correlated with disease duration (P= 0.023), ASDAS score (P<0.0001), DAPSA score (P= 0.0001), CRP (P<0.0015) and ESR (P<0.0001) .

Conclusion: We found that the side effects of COVID-19 vaccines are similar between AS/PsA patients and healthy population. However, these patients showed a notably weaker vaccine response, particularly those with higher disease activity and a longer duration of the disease. The type of vaccine used did not affect the response, nor did the use of IL-17 inhibitors or anti-TNF treatments. Healthcare professionals should recommend COVID-19 vaccination to rheumatic patients, as the benefits of vaccination far outweigh the minimal risk of potential side effects

Key Words: Ankylosing spondylitis, COVID-19, Psoriatic arthritis, Vaccine.

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INTRODUCTION

The coronavirus, officially known as SARS-Cov-2, is a highly infectious virus that prevailed in 2019 and caused the global COVID-19 pandemic. The virus primarily spreads through respiratory droplets, leading to variable clinical manifestations ranging from mild flu-like symptoms to extensive pneumonia and severe respiratory distress[1].

The risk of COVID 19 infection in spondylarthropathy(SpA) patients including ankylosing spondylitis (AS) and psoriatic arthritis (PsA) has been the subject of ongoing research. Some studies suggest rheumatic diseases patients may have an increased susceptibility to corona virus infection due to both the underlying immune dysregulation and the immunosuppressive therapies often used in the management. However, other studies stated that SpA patients are not necessarily at higher risk of

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developing COVID19 than the general population, but they may have a higher likelihood of complications and wor se outcomes[2].

Preventable diseases vaccination is particularly recommended for all systemic rheumatic diseases patients, except for using live vaccines together with certain immunomodulatory therapies[3].

Because of the paucity of safety and efficacy data on the use of COVID-19 vaccines in patients with rheumatic diseases, there is a debate whether these patients may truly benefit from the vaccine[4]. There is a question about whether immunosuppressive therapies such as corticosteroids, DMARDS, and biologics could affect the response to the COVID-19 vaccine or potentially trigger an aggravation of disease activity. However, Vaccination against COVID-19 infection was recommended recently for the vast majority of patients with systemic rheumatic diseases by The American College of Rheumatology (ACR)[5].

THE AIM THE STUDY

The aim of this study was to evaluate the response to COVID19 vaccine in psoriatic and ankylosing spondylitis patients regarding effectiveness and side effects.

PATIENTS AND METHODS

A case control study included 50 patients between 18-60 years with SPA (psoriatic arthritis according to CASPAR criteria[6] and ankylosing spondylitis according to ASAS-EULAR criteria[7], and 50 matched healthy controls. Patients with connective tissue diseases and autoimmune diseases other than AS &PsA were excluded from the study. Patients were recruited from the Rheumatology department Ain Shams University hospital and Maadi military hospital over a period of 6 months.

Regarding the patient group, full medical history and full clinical examination was performed, emphasizing on comorbidities, any side effects or disease flare symptoms 6 weeks after vaccination. Disease activity was measured using (ASDAS) the Ankylosing Spondylitis Disease Activity Score[8] and (DAPSA) Disease Activity in Psoriatic Arthritis Score[9]. Laboratory investigations including ESR, CRP titre,CBC, Serum creatinine, AST and ALT were done.

Type of vaccine and any vaccine side effect was recorded for all participants.

Measuring COVID-19 serum IgG antibody was performed for all participants, patients with IgG level ≥ 78AU/mL are considered respondent and patients with IgG level ≥ <78AU/mL are considered non respondent according to the manufacturer's instructions.

ETHICS COMMITTEE

The research ethics committee, Ain Shams University hospital, approved the study ,the approval number (FWA000017585/ FMASU M S 618/2021), All participants provided their written informed consent.

Statistical Analysis: Data were enterd to Statistical Package for Social Science (SPSS) version 20. Qualitative data were presented as percentages and numbers, while the quantitative were presented as mean, standard deviations, and ranges. Comparison between the two groups with qualitative data was done using chi-square test, and When the expected count in any cell was < 5 Fisher exact test was used. The comparison between 2 quantitative data with parametric distribution was done using independent T-test. *P-value* ≤ 0.05 was considered significant.

RESULTS

One hundred subjects were registered for this study, divided into two equal groups (Control group and Cases 'Seronegative arthropathy' group). The two groups were matched for age and sex. Demographic data of all participants is shown in (Table 1).

Table 1: Demographic data of the participants.

Variable		Control group (50)	Cases group (50)	*P value*
		Median (IQR)	Median (IQR)	
Age (years)		37 (29 – 50)	42 (35 – 53)	= 0.1078
Gender	Female	21 (42%)	15 (30%)	= 0.2136
	Male	29 (58%)	35 (70%)	

Table 2: Comorbidities of the participants.

Variable	Control group (50)	Cases group (50)
Family history for rheumatic diseases	0 (0%)	15 (30%)
Smoking	15 (30%)	17 (34%)
DM	15 (30%)	10 (20%)
HTN	15 (30%)	16 (32%)

Only 10 patients of the cases group (20%) and 5 patients (10%) of the control group did not have any adverse effects after the vaccine. Vaccination data of the participants is shown in (Table 3).

Table 3: Comparison between the cases and the control group regarding vaccination data.

Variable		Control group (50)	Cases group (50)	*P value*
Type of vaccine	AstraZeneca	5 (10%)	8 (16%)	= 0.2675
	Sinopharm	15 (30%)	20 (40%)	
	Sputnik	30 (60%)	22 (44%)	
Doses of vaccine	1	0 (0%)	0 (0%)	= 1.0000
	2	50 (100%)	50 (100%)	
Adverse effects		45 (90%)	40 (80%)	= 0.161
Type of adverse effects (within 6 weeks)	None	5 (10%)	10 (20%)	
	Body aches	14 (28%)	14 (28%)	= 1.00
	Chills	12 (24%)	12 (24%)	= 0.648
	Diarrhea	12 (24%)	12 (24%)	= 1.00
	Fatigue	18 (36%)	15 (30%)	= 0.523
	Fever	5 (10%)	6 (12%)	= 0.749
	Headache	14 (28%)	10 (20%)	= 0.349
Vaccine response	Non-respondent	5 (10%)	10 (20%)	= 0.161
	Respondent	45 (90%)	40 (80%)	

The cases group had significantly lower 88.2 mg/dL (78 – 90.1) IgG serum levels than the control group. 93.8 mg/dL (92 – 95), *P*< 0.0001. Laboratory data of the participants are shown in (Table 4).

Table 4: Comparison between the control and cases groups as regard lab data.

Variable	Control group (50)	Cases group (50)	*P value*
	Median (IQR)	Median (IQR)	
Hb (g/dL)	13.1 (12.3 – 14)	12 (10.8 – 13)	< 0.0001**
PLT (103/µL)	245 (212 – 301)	247 (220 – 312)	= 0.8766
TLC (103/µL)	8 (5.2 – 9.1)	7.6 (5.9 – 9.3)	= 0.9449
ESR (mm/h)	6 (4 – 10)	20 (16 – 60)	< 0.0001**
CRP (mg/dL)	3.2 (2.2 – 4)	3.9 (2.6 – 28.6)	= 0.027*
s.Creatinine (mg/dL)	0.7 (0.5 – 0.9)	0.8 (0.6 – 0.9)	= 0.5788
AST (U/L)	17 (14 – 20)	19 (16 – 26)	= 0.0043**
ALT (U/L)	18.5 (18 – 21)	22 (19 – 30)	= 0.0081**
IgG antibody level (mg/dL)	93.8 (92 – 95)	88.2 (78 – 90.1)	< 0.0001**

Most of patients 36 (72%) in the cases group were on NSAIDs as shown in (Table 5). Serum IgG antibody levels significantly negatively correlated with disease duration, platelet count, ESR, CRP, ASDAS-CRP score and DAPSA score as shown in (Table 7) and graphs (1-6).

Table 5: Drug history among the cases group.

Variables	Frequency (%) / Mean (range)
Steroid	4 (8%)
Daily dose (mg/day)	2 (0 – 15)
Steroid duration (years)	1.8 (0 – 13.5)
Cumulative dose (mg)	7555 (0 – 71175)
NSAIDs	36 (72%)
HCQ	0 (0%)
SSZ	14 (28%)
MTX	12 (24%)
Leflunomide	0 (0%)
Anti-TNF	14 (28%)
Anti-IL-17	21 (42%)

NSAIDs: non-steroidal anti-inflammatory drugs; HCQ: hydroxy-chloroquine; MTX: methotrexate; SSZ: salazopyrin; IL: interleukin; TNF: tumor necrosis factor.

Table 6: Disease activity among the cases group.

Variables	Mean ± SD	Range
ASDAS-CRP score (AS)	2.2 ± 1	(1.1 - 4.1)
DAPSA score (PsA)	13.6 ± 10.6	(3.6 - 28)

ASDAS score: The Ankylosing Spondylitis Disease Activity Score; DAPSA: Disease Activity index for Psoriatic Arthritis.

Table 7: Correlation analysis between IgG antibody level and other parameters.

Associated Factor	IgG antibody level	
	Spearman's rho	*P value*
Age (years)	0.0677	=0.5034
Disease duration (months)	-0.320	=0.023*
ASDAS-CRP score (AS)	-0.641	<0.0001**
DAPSA score (psoriatic arthritis)	-0.821	=0.0001**
Hb (g/dL)	0.0685	=0.4985
PLT (103/µL)	-0.198	=0.0481*
TLC (103/µL)	-0.0719	=0.4772
ESR (mm/h)	-0.669	<0.0001**
CRP (mg/dL)	-0.313	=0.0015**
Creatinine (mg/dL)	0.0593	=0.5581
AST (U/L)	-0.147	=0.1437
ALT (U/L)	-0.0458	=0.6508

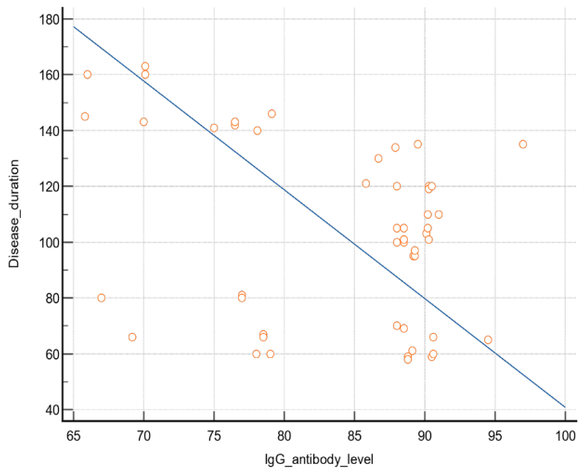

Fig. 1: Correlation between IgG antibody level and disease duration.

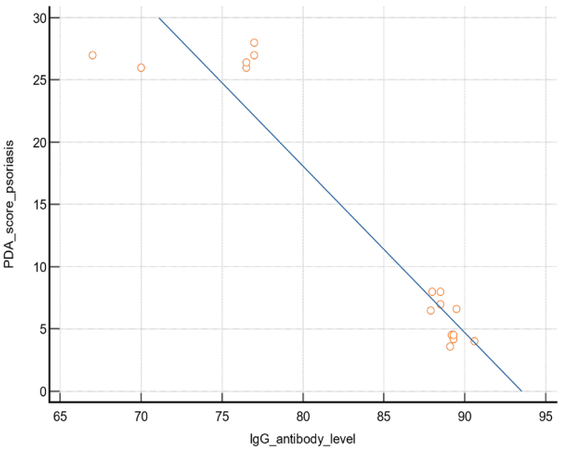

Fig. 3: Correlation between IgG antibody level and DAPSA score (psoriasis).

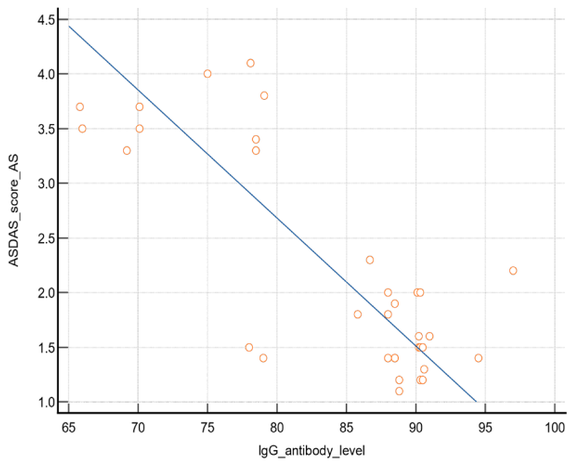

Fig. 2: Correlation between IgG antibody level and ASDAS-CRP score (AS).

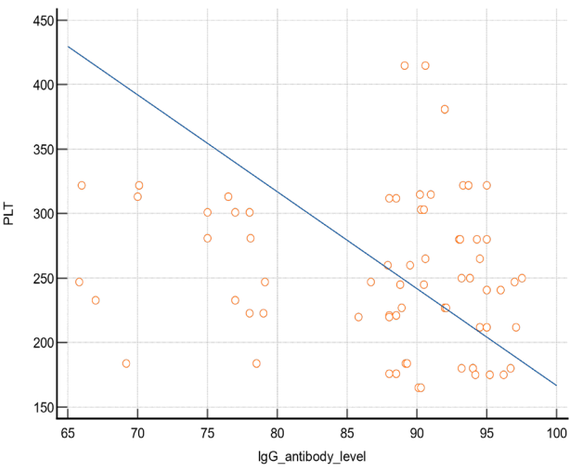

Fig. 4: Correlation between IgG antibody level and PLT.

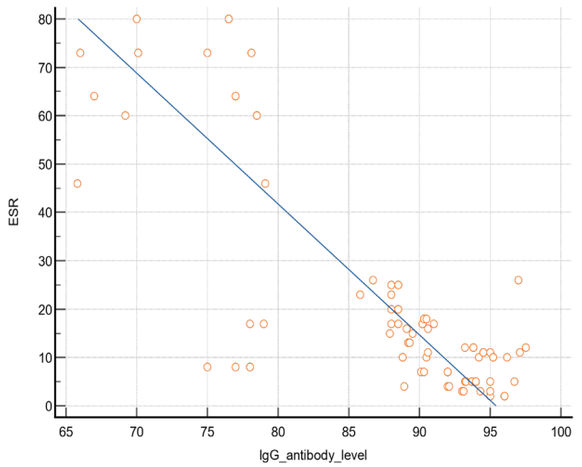

Fig. 5: Correlation between IgG antibody level and ESR.

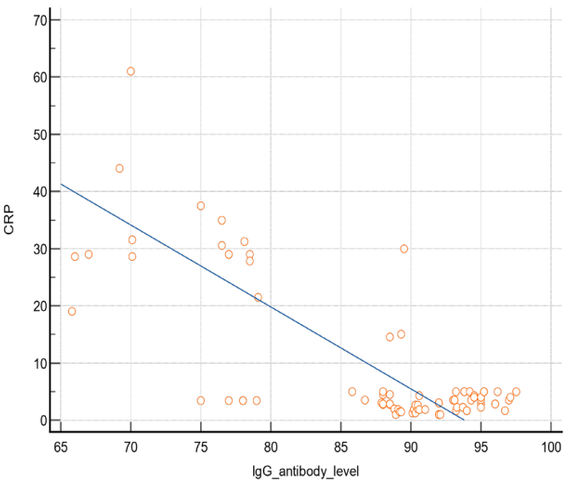

Fig. 6: Correlation between IgG antibody level and CRP.

IgG antibody levels were not different in cases receiving different types of vaccine or different biologic therapy as in (Table 8).

Table 8: IgG antibody levels in cases receiving different types of vaccine/ biologic therapy.

	IgG antibody level (mg/dL) Median (IQR)	*P value*
Type of vaccine:		
Sinopharm	87.95 (75.75 - 89.3)	0.595
Sputnik	88.8 (79 – 90.2)	
AstraZeneca	88.25 (78.5 – 89.55)	
Type of Biologic therapy:		
Anti TNF	89.3 (85.8 - 90.3)	0.363
Anti IL-17	88.5 (78.5 - 89.2)	

DISCUSSION

The development of COVID-19 vaccines has significantly reduced covid 19 infection morbidities and mortalities. Rheumatic diseases patients had a strong recommendations for vaccinatation according to the new guidlines because they are more susciptable to corona virus infection and complications[10].

Therefore, the aim of this study is to assess effectiveness and side effects of COVID19 vaccines in ankylosing spondylitis and psoriatic arthritis patients.

In relation to clinical data and demographic data of the cases group, this study mentioned that the mean age of cases group was 42.76 ± 11.86 years, (70%) of patients were males. 30% of patients had positive family history of autoimmune illness, (20%) had DM, (32%) had HTN, and (34%) were smokers. This result is in agreement with Fong et al who estimated that during the retrospective multi-center study to assess prevalence and factors associated with disease activity post COVID-19 mRNA vaccination in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and spondyloarthritis (SpA) patients , the median (IQR) age of a total of 2377 patients was 62.0 (52.0–71.0) years and 820 (34.5%) were male subjects[11].

In our study, (16%) of patients had AstraZeneca, (40%) had Sinopharm, (44%) had Sputnik, and all patients received 2 doses. In this context, a meta-analysis conducted to assess the clinical symptoms of new-onset arthritis occurring after COVID-19 vaccination following at least one dose of COVID-19 vaccine,percentage of (84.4%) of thepatients received AstraZeneca[12]. In addition, Fong et al did a study which included a known RA, PsA or SpA patients and estimated that (87.6%) patients received

the Pfizer vaccine and (93.2%) received two doses of vaccine[11].

We assessed Disease activity of 50 cases, 34 patients with AS by the ASDAS-CRP score (2.2 ± 1) and ranged from 1.1 to 4.1, and 16 patients with PsA by the DAPSA score (13.6 ± 10.6) and ranged from 3.6 to 28. In agreement with us, disease activity in a study of axial SpA/psoriatic arthritis to evaluate anti-covid 19 IgG seropositivity, it was estimated that (54.6%) of patients had ankylosing spondylitis while (45.4%) Of them had psoriatic arthritis. Disease activity of the included patients measured by ASDAS-CRP and DAPSA, were 2.0 ± 1.1 and 13.9 ± 14.5, respectively[13].

We performed a correlation analysis regarding IgG antibody level and other measured parameters which showed that; disease duration, ASDAS-CRP score, DAPSA score, platelet count, ESR, CRP, and Sinopharm usage, had a highly significant negative correlation with IgG antibody level.

The laboratory findings of the comparative analysis in our study revealed that there was significantly higher ESR, CRP, AST, and ALT, while significantly lower hemoglobin and COVID-19 IgG anti-body level in cases group in comparison to control group. In agreement with us, meta-analysis for determining serologic response to COVID-19 vaccination in autoimmune rheumatic diseases patients demonstrated that the rate of seroconversion in these patients was statistically lower compared with controls[14]. In alignment, a recent systematic review of case reports confirmed our significant results and noted that two nonspecific inflammatory markers; ESR and CRP, were estimated in t all cases, and all patients showed diferrent degrees of increase in the two markers[12]. ***Xie et al.*** also investigated the flare development for patients with rheumatic diseases may be stimulated by the COVID-19 vaccine, especially for those who already had a high disease activity and recorded an increased disease activity and side effects post vaccination[15].

Different to us, ***Li et al.*** conducted a study including 5493 patients with rheumatic diseases to investigate the association between COVID-19 vaccination with two completed doses and possible arthritis occurance, he found a non significant relationship between arthritis and the complete vaccination of mRNA or inactivated virus COVID-19 vaccines[16].

Several previous studies had studied different other risk factors that increase the likelihood of flare-ups in rheumatic patients after vaccination. These factors include old age, female gender, history of allergies, previous history of infection with SARS-CoV-2, stressful situations, and poor adherence to treatments[4].

In the current study, 80% of patients in the cases group had various adverse effects after vaccination, including Fatigue 30%, Body aches 28%, Chills 24%, Diarrhea 24%, Headache 20%, and Fever 12%.

In difference with the previous findings, in a survey to assess the safety and disease flare in patients with autoimmune rheumatic diseases who received any of the inactivated COVID-19 vaccines in China, it was recorded that the joint pain (61/158, 38.6%) and the swelling (31/158, 19.6%) were the common charasterestics of the flare, followed by skinrash (27/158, 17.1%), morning stifness (20/158, 12.7%) and fever(14/158, 8.9%)[17].

In the cases group in our study, patients on non-steroidal anti-inflammatory drugs (NSAIDs) (72%), Steroids (8%), methotrexate (24%), salazopyrin (28%), Anti- interleukin 17(42%) and Anti TNF (28%). In the same line with our results, ***Liu et al.*** illustrated that most patients received glucocorticoid drugs or NSAIDs[12]. Also, cases therapy in a previous study by Saad et al were steroid (8.2%), NSAID (40.4%), Sulfasalazine (22.4%), Immunosuppressive drugs (40.4%), MTX (29.0%), and TNFi(39.9%). by ***Saad et al.***[13].

Cases group in our study using DMARDs, Anti-TNF and IL17 inhibitor showed significantly lower IgG antibody level in comparison to control group, while therewas non-significant difference between patients on either anti TNF and IL-17 inhibitor as well as between three types of vaccine. A cohort study for (RA, PsA, and SpA) patients who received the SARS-CoV-2 vaccine illustrated that patients receiving both cs/bDMARD were at high risk of lower response to SARS-CoV-2 vaccines by measuring IgG level in comparison to patients without DMARD treatment that agrees with our results[18]. In agreement with our findings, Saad et al illustrated that prednisone, MTX and TNF inhibitors were associated with alower antiSARS-CoV2 IgG seropositivity[13].

As regard our comparative study between the 2 subgroups (PsA, AS) confirmed a non-significant difference regarding the vaccine response and adverse effects whatever the type of vaccine used. This goes along with results of a cross-sectional study investigating safety of COVID-19 vaccine among pediatric patients with inflammatory rheumatic diseases, they estimated that there is no significant difference between mRNA and inactivated vaccines[19].

CONCLUSION

We conclude that COVID-19 vaccines side effects don't differ between AS/PsA patients from healthy controls. However, these patients had a significantly lower

vaccination response than controls, especially in those with ahigher diseaseactivity and longerdisease duration. The vaccination response also did not differ between different vaccine types, and whether patients were receiving IL 17 inhibitor or anti TNF. Healthcare providers should encourage patients to receive thevaccine ofCOVID-19, since the potential benefit of the low risk of the related vaccine adverse effects.

CONFLICT OF INTERESTS

There is no conflicts of interest.

AUTHOR CONTRIBUTIONS

All authors Contributed in this manuscript and spared no effort to make it best

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ما بعد تطعيم كوفيد_19 "فايروس كورونا" لمرضى الالتهاب الفقاري المُقسِّط والتهاب المفاصل الصدفي

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الخلفية: كان خطر الإصابة بـكوفيد19- لدى الأفراد المصابين بالتهاب الفقار المقسط والتهاب المفاصل الصدفي، محورًا للدراسات المستمرة. نظرًا لقلة بيانات السلامة والفعالية حول لقاح كوفيد19- لدى المرضى الذين يعانون من أمراض روماتيزمية جهازية، بالإضافة إلى المخاوف الخاصة المتعلقة باستخدام مثبطات المناعة، قد تكون هناك اختلافات مهمة في المواقف تجاه التطعيم ضد كوفيد19- بين المرضى الذين يعانون من أمراض روماتيزمية جهازية وعامة السكان.
الهدف: دراسة استجابة لقاحات كوفيد19- لدى مرضى التهاب المفاصل الصدفي والتهاب الفقار اللاصق فيما يتعلق بالفعالية والآثار الجانبية.
المشاركون وطرق البحث: هذه دراسة حالة-ضابطة شملت 50 مريضًا بالتهاب المفاصل الصدفي والتهاب الفقار اللاصق و50 من الأصحاء المطابقين في العمر والجنس. تم تسجيل نوع اللقاح، وأي آثار جانبية المرض لمدة 6 أسابيع بعد التطعيم لجميع المشاركين. تم قياس نشاط المرض باستخدام درجة نشاط مرض التهاب الفقار اللاصق (ASDAS) ودرجة نشاط المرض في التهاب المفاصل الصدفي (DAPSA). تم إجراء قياس مستوى الأجسام المضادة IgG المصلية لكوفيد19- لجميع المشاركين.
النتائج: كانت مستويات IgG المصلية لكوفيد19- بعد التطعيم أقل بكثير في مجموعة الحالات 88.2 ملغ/ديسيلتر (78 - 90.1) مقارنة بالمجموعة الضابطة 93.8 ملغ/ديسيلتر (92 - 95). لم يكن هناك فرق كبير بين المجموعتين فيما يتعلق بالآثار الجانبية للقاح أو الاستجابة. ارتبطت مستويات الأجسام المضادة IgG لكوفيد19- بشكل سلبي كبير مع مدة المرض، ودرجة ASDAS، ودرجة DAPSA ، وسرعة ترسب الدم، وبروتين سي التفاعلي.
الاستنتاج: وجدنا أن الآثار الجانبية للقاحات كوفيد19- متشابهة بين المرضى المصابين بالتهاب الفقار اللاصق/التهاب المفاصل الصدفي والأفراد الأصحاء. ومع ذلك، أظهر هؤلاء المرضى استجابة أضعف بشكل ملحوظ للقاح، خاصة أولئك الذين يعانون من نشاط مرض أعلى ومدة مرض أطول. لم يؤثر نوع اللقاح المستخدم على الاستجابة، ولا استخدام مثبطات IL-17 أو علاجات مضادات عامل نخر الورم. يجب على المتخصصين في الرعاية الصحية التوصية بالتطعيم ضد كوفيد19- للمرضى الروماتيزميين، حيث تفوق فوائد التطعيم بكثير المخاطر الضئيلة للآثار الجانبية المحتملة.