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COVID-19 VACCINE-RELATED MUSCULOSKELETAL MANIFESTATIONS

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ABSTRACT

Objective/Aim: We investigated the new onset musculoskeletal reactions after SARS-cov-2 vaccination in patients with and without pre-existing autoimmune inflammatory rheumatic diseases (AIIRD). **Methods:** 200 participants, of whom 100 patients diagnosed with rheumatoid arthritis (RA) or spondyloarthritis (SpA) at least 6 months before covid-19 pandemic. The inclusion period was from March 2023 to August 2024. A questionnaire regarding musculoskeletal reactions following the SARS-cov-2 vaccine was completed by the participants. **Results:** Of the 200 participants, 100 were diagnosed with AIIRD (71 RA and 29 SpA) and 100 were healthy control (patients with no previous antecedent of AIIRD). Antecedent of covid-19 infection was noted in 26% patients with AIIRD and 11.7% patients-control. Compared with health care participants, the prevalence of patients with AIIRD who received the covid-19 booster with the fourth dose was higher (17% versus 2%). Fear over the vaccine's side effects was the most common cause of discontinuing the vaccination protocol in individuals with and without AIIRD for the first three doses. Overall, 30 musculoskeletal reactions following covid-19 vaccination have been reported. Of whom 24 were followed for RA or SpA. fourth patients experienced mild reactivation of arthritis after vaccination. Arthralgia was the most common reported musculoskeletal reaction. One patient developed erosive seronegative RA difficult to treat. AstraZeneca vaccine administration was reported in most of the musculoskeletal cases. Antecedent of covid-19 infection and the pre-existing AIIRD increased the risk of developing post covid-19 musculoskeletal manifestations (p=0.03, p=0.001 respectively). **Conclusion:** This study reports a low occurrence of new-onset musculoskeletal reactions post covid-19 vaccines.

KEYWORDS: Covid-19 vaccine, musculoskeletal manifestations, rheumatoid arthritis, spondyloarthritis, autoimmune inflammatory rheumatic diseases.

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS cov-2) has overwhelmed the globe since late 2019. Large-scale worldwide covid-19 vaccination programs were swiftly developed and approved as a result of the covid-19 pandemic.[1–3] Adenoviral vector vaccines (AstraZeneca, Johnson Pharma), mRNA vaccines (Pfizer, Moderna), and inactivated whole-virus vaccines (Sinopharm, Sinovac) were the primarily included vaccines. The incidence of covid-19 infection, transmission, hospitalizations, and deaths worldwide had been notably reduced since the introduction of these covid-19 vaccines. Although, the safety of these vaccines had been widely supported by studies of the European (EULAR) and American (ACR) rheumatology societies in healthy individuals and patients followed for autoimmune inflammatory rheumatic diseases (AIIRD), various case reports had linked these vaccines to osteoarticular adverse effects, such us the onset of immune adverse reactions and a flare-up of existing AIIRD.[4–7] These reactions are often under or misdiagnosed with a missing data in the real esteem of their true incidence and treatment strategy.[1,8,9]

In light of this, this study endeavors to identify plausible links between covid-19 vaccines and the onset or exacerbation of musculoskeletal manifestations in individuals with and without AIIRD.

MATERIALS AND METHODS

1. Study design

We conducted a single-center retrospective study screening individuals 18 years of age and older, encountered in routine clinical practice. Data were obtained from one center (Military Hospital Mohammed V, Ibn Sina University Hospital) in the capital of Morocco. We administered a questionnaire about vaccination to evaluate the musculoskeletal symptoms

after covid-19 vaccination. There were two categories of participants: AIIRD group (patients diagnosed with RA or SpA at least 6 months before covid-19 pandemic who fulfilled ACR/EULAR 2010 criteria and ASAS 2009 criteria respectively) and healthy control group (patients with no previous history of AIIRD).

Information about demographic and clinical characteristics of participants including age, comorbidities, as well as characteristics of RA and SpA and the medications they were taking csDMARD, bDMARD, corticosteroids and non steroidal anti-inflammatory drug use, were obtained from patient medical records. Patients were asked if they developed any musculoskeletal symptom after any of the four doses and up to 3 months after each dose and the treatment used to manage. RA and SpA patients reported also whether they experienced post vaccine flares and if these flares required treatment. Flare was defined as developing joint pain associated with swelling and morning stiffness similar to prior RA and SpA flares and worsening of disease activity scores.

The study period was from March 2023 to August 2024. We obtained written informed consent from all patients. The study complies with the Helsinki humanity research declaration, 2008.

2. Statistical analysis

JAMOVI software was used for the statistical analyses. We presented Continuous variables as mean (standard deviation) and non-continuous variables as medians (interquartile ranges). Categorical parameters were reported as absolute number and percentage. We used Kolmogorov-Smirnov test to verify normal distribution of the data.

Chi-squared test or Fischer's exact test were used to compare prevalence of covid-19 vaccine between patients with AIIRD and patients without AIIRD. p-value less than 0.05 was defined as Statistical significance.

We performed a univariable followed by multivariable logistic regression analysis to identify potential factors related to musculoskeletal reactions; only characteristics with a p-value <0.20 in the univariable analysis were entered in the multivariable analysis.

RESULTS

200 patients were included, 100 participants with AIIRD (71 RA, 29 SpA) and 100 participants with no history of AIIRD. History of covid-19 infection was noted in 26% participants with AIIRD and 11.7% participants without AIIRD. Personal or familial antecedent of autoimmune disease was noted in six patients with AIIRD (fourth autoimmune thyroiditis, one behcet, one inflammatory bowel disease) and 14 patients without AIIRD (eight autoimmune thyroiditis, two inflammatory bowel disease, one autoimmune thyroiditis, one RA, one lichen planus, one psoriasis). At the first dose of covid-19 vaccine, remission were noted in all RA and SpA patients; the median of DAS28 CRP, BASDAI and ASDAS CRP were 0.6, 1.1 and 0.8 respectively. The antirheumatic treatments used were csDMARDs (61%), bDMARDs (41%), Corticosteroids (44%) and NSAIDs (19%). (Table 1).

Table 1 : Baseline of patients with AIIRD (RA or SpA) (a) and patients without AIIRD (b).
(a)

Characteristics	Value (N=100)
Age [a] (years) (N=100)	53.2± 13.2
Gender [b] (N=100)	
Male	39 (39)
Female	61 (61)
Antecedent of covid-19 infection [b] (N=100)	26 (26)
Number of past covid-19 infection [b] (N=26)	
1	23 (88.4)
2	2 (7.6)
3	-
4	1 (3.8)
Personel or familial antecedent of autoimmune disease [b] (N=100)	6 (6)
Autoimmune thyroiditis	4 (4)
Autoimmune hepatitis	-
Inflammatory bowel disease	1 (1)
Behcet	1 (1)
Lichen planus	-
Familial antecedent of chronic joint disease	-
Type of pre-existing chronic joint disease	
Rheumatoid arthritis [b]	71 (71)
Seropositive [b] (N=71)	52 (73.2)
Erosion [b] (N=71)	41 (57.7)

Disease duration [c] (months) (N=71)	132 [60-228]
Spondyloarthritis [b]	29 (29)
Axial spondyloarthritis [b] (N=29)	26 (89.7)
Peripheral spondyloarthritis [b] (N=29)	3 (10.3)
Inflammatory bowel disease [b] (N=29)	3 (10.3)
Uveitis [b] (N=29)	5 (17.2)
Psoriasis [b](N=29)	3 (10.3)
Disease duration [c] (months) (N=29)	72 [33-144]
Covid-19 vaccine ever [b]	96 (96)
Activity of chronic joint disease at the first dose of anti covid-19 vaccine [c]	
DAS28 CRP (N=70) BASDAI (N=28)	0.6 [0.2-0.8] 1.1 [0.8-1.9]
ASDAS CRP (N=25)	0.8 [0.6-1.0]
Curent treatment at the first dose of anti covid-19 vaccine [b] (N=100)	
NSAID	
Corticosteroids	19 (19)
csDMARD	44 (44)
bDMARD	61 (61) 41 (41)

(b)

Characteristics	**Value (N=100)**
Age [a] (years) (N=100)	52 ±12.5
Gender [b] (N=100)	
Male	32 (32)
Female	68 (68)
Antecedent of covid-19 infection [b] (N=100)	18 (18)
Number of past covid-19 infection [b]	
1	
2	15 (15)
3	3 (3)
4	-
Personel or familial antecedent of autoimmune disease [b] (N=100)	14 (14)
Autoimmune thyroiditis	8 (8)
Autoimmune hepatitis	1 (1)
Inflammatory bowel disease	2 (2)
Behcet	-
Lichen planus	1 (1)
Psoriasis	1 (1)
Familial antecedent of chronic joint disease	1 (1)
Covid-19 vaccine ever [b]	98 (98)
Number of covid-19 vaccine (N=98)	
1	11 (11.2)
2	30 (30.6)
3	57 (58.1)

[a] Mean and standard deviation; [b] Number and percentage valid.

For the first three doses of the covid-19 vaccine, there were no significant differences in the prevalence of vaccination between patients with AIIRD and those without. When 17% patients with AIIRD received the covid-19 booster with the fourth dose, only 2% of patients without AIIRD had received the fourth dose. (Table 2).

Table 2: Comparison of prevalence of covid-19 vaccine between patients with AIIRD (RA or SpA) and patients without AIIRD.

	Patients with AIIRD	Patients without AIIRD	p
First vaccine dose [a]	95 (95)	94 (94)	0.75
AstraZeneca	55 (55)	37 (37)	
Synopharm	35 (35)	53 (53)	
Pfizer	1 (1)	2 (2)	
Johnssons & Johnsons	1 (1)	-	
Second vaccine dose [a]	89 (89)	89 (89)	0.60
AstraZeneca	49 (49)	31 (31)	
Synopharm	35 (35)	49 (49)	
Pfizer	1 (1)	4 (4)	
Johnssons & Johnsons	1 (1)	-	
Third vaccine dose [a]	53 (53)	56 (56)	0.67
AstraZeneca	13 (13)	10 (10)	
Synopharm	24 (24)	22 (22)	
Pfizer	10 (10)	14 (14)	
Johnssons & Johnsons	-	-	
Forth vaccine dose [a]	17 (17)	2 (2)	<0.001
AstraZeneca	4 (4)	1 (1)	
Synopharm	6 (6)	1 (1)	
Pfizer	5 (5)	1 (1)	
Johnssons & Johnsons	-	-	

AIIRD: autoimmune inflammatory rheumatic diseases; RA: rheumatoid arthritis; SpA: spondyloarthritis.
[a] Number and percentage valid $p<0.05$ is considered significant.

The statistical test used: Chi-squared test or Fischer's exact test.

Fear over the vaccine's side effects was the most common cause of discontinuing the vaccination protocol in both patients with AIIRD (first dose: 40%; second dose: 66.9%; third dose: 86.2%) and patients without AIIRD (first dose: 100%; second dose: 100%; third dose: 91.4%). (Table 3).

Table 3: Causes of discontinuing the covid-19 vaccine program in patients with AIIRD (RA or SpA) and patients without AIIRD.

Causes	Value
Patients with AIIRD	
First dose [a] (N=5)	
Fear of vaccine's side effects	2 (40)
There were contraindications to vaccination.	1 (20)
Pregnancy	-
Not informed	1 (20)
Other	1 (20)
Second dose [a] (N=9)	
Fear of vaccine's side effects	6 (66.9)
There were contraindications to vaccination.	1 (11.1)
Pregnancy	-
Not informed	1 (11.1)
Other	1 (11.1)
Third dose [a] (N=29)	
Fear of vaccine's side effects	25 (86.2)
There were contraindications to vaccination.	1 (3.4)
Pregnancy	-
Not informed	2 (6.9)
Other	1 (3.4)
Fourth dose [a] (N=57)	
Fear of vaccine's side effects	25 (43.9)
There were contraindications to vaccination.	1 (1.7)
Pregnancy	-

Not informed	30 (52.7)
Other	1 (1.7)
Patients without AIIRD	
First dose [a] (N=3)	
Fear of vaccine's side effects	3 (100)
There were contraindications to vaccination.	-
Pregnancy	-
Not informed	-
Other	-
Second dose [a] (N=6)	
Fear of vaccine's side effects	6 (100)
There were contraindications to vaccination.	-
Pregnancy	-
Not informed	-
Other	-
Third dose [a] (N=35)	
Fear of vaccine's side effects	32 (91.4)
There were contraindications to vaccination.	-
Pregnancy	2 (5.7)
Not informed	1 (2.9)
Other	-
Fourth dose [a] (N=59)	
Fear of vaccine's side effects	13 (22)
There were contraindications to vaccination.	-
Pregnancy	-
Not informed	46 (78)
Other	-

[a] Number and percentage valid.

We identified 30 musculoskeletal reactions following covid-19 vaccination. 24 of them (80%) were followed for RA or SpA. fourth patients experienced mild reactivation of arthritis after vaccination: one of them after receiving the second vaccine dose, and the three others only after the first dose. These flares resolved with oral corticosteroids without hospital admission or a readjustment of their background DMARDs. Overall, post vaccination joint involvement varied among cases: arthralgia was the most common reported reaction 22 (73.3%). This included shoulder, elbow, ankle, metacarpophalangeal, proximal and distal interphalangeal joints. Other reported musculoskeletal reactions were one lower back pain, one diffuse myalgia. Clinical remission was reported in 27 of the 30 cases (90%). One patient developed erosive seronegative RA, based on classification criteria, difficult to treat. she experienced an initial oligoarthritis presentation without inflammatory syndrome refractory to csDMARDs and three bDMARDs (etanercept, adalimumab, rituximab) with partial improvement with anti-JAK. (Table 4).

AstraZeneca vaccine administration was noted in most of the musculoskeletal cases, accounting for 18 (60%) cases, Synoharm was reported in eight cases (26.7%), whereas Pfizer was administrated in fourth cases (13.3%). Musculoskeletal symptoms were developed after an average of 24 days after the first and the third dose and 27 days after the second dose. (Table 4).

Table 4: Demographics and characteristics of patients with new onset musculoskeletal manifestations following covid-19 vaccine.

Parameter	**Value (N=30)**
Age [a] (years)	50 [40-65]
Gender [b]	
Male	14 (46.6)
Female	16 (53.4)
Pre-vaccine SpA or RA [b]	
None	0
Present	24 (80)
Pre-vaccine other auto-immune disease [b]	
None	0
Present	4 (13.3)
Type of vaccine [b]	

AstraZeneca	18 (60)
Synopharm	8 (26.7)
Pfizer	4 (13.3)
Doses of vaccine received [b]	
1	9 (30)
2	16 (53.4)
3	5 (16.6)
Days from vaccine to symptoms onset [a]	
After 1st dose	24 [3.5-168]
After 2nd dose	27 [6-43]
After 3rd dose	24 [4-36]
Type of musculoskeletal manifestations following covid-19 vaccine [b]	
RA or SpA flare-up	4 (13.3)
RA onset	1 (3.3)
Mono arthralgia	3 (10)
Oligo arthralgia	13 (43.3)
Polyarthralgia	6 (20)
Lower back pain	2 (6.6)
Myalgia	1 (3.3)
First line treatment of musculoskeletal manifestation [b]	
Oral antalgic	15 (50)
Oral NSAIDs	4 (13.3)
Oral corticosteroids	4 (13.3)
No medication	7 (23.3)
Response to the the first line treatment [b] (N=23)	
Responsive	20 (86.9)
Unresponsive	3 (13.1)

AIIRD: autoimmune inflammatory rheumatic diseases; NSAIDs : non steroidal anti-inflammatory drugs; RA: rheumatoid arthritis; SpA: spondyloarthritis.

[a] Median and interquartile ranges; [b] Mean and standard deviation ; [c] Number and percentage valid.

Multivariate logistic analysis, adjusted for age, history of auto-immune disease, number of covid-19 infection showed an association between musculoskeletal manifestations following covid-19 vaccine and antecedent of covid-19 infection and pre-existing RA or SpA (p=0.03, p=0.001 respectively). (Table 5).

Table 5: Factors associated with new onset musculoskeletal manifestations following covid-19 vaccine (univariable (a) and multivariable analysis (b)).

(a)

	OR	95% CI for OR	p
Age	0.99	0.96-1.02	0.59
Gender	0.54	0.24-1.24	0.15
History of auto-immune disease	1.96	0.59-6.47	0.26
Antecedent of covid-19 infection	3.48	1.44-8.39	0.005
Numbrer of covid-19 infection	0.47	0.06-3.29	0.44
Pre-existing RA or SpA	7.26	2.4-21.8	<0.001

(b)

	OR	95% CI for OR	p
Gender	0.39	0.15-0.99	0.051
Antecedent of covid-19 infection	2.75	1.06-7.13	0.03
Pre-existing RA or SpA	7.49	2.39-22.51	0.001

RA : rheumatoid arthritis ; SpA : spondyloarthritis
$p<0.05$ is considered significant.

The statistical test used: univariable logistic regression (a) and multivariable logistic regression (b).

DISCUSSION

On 28 January 2021, covid-19 vaccines were first introduced to Morocco and used for individuals 18 years and above. Five vaccines were available: inactivated virus vaccine (Beijing CNBG's BBIBP-CorV), virus vectored vaccines (AstraZeneca's Vaxzevria and Gamaleya's Gam-COVID-Vac), mRNA vaccine (Pfizer-BioNTech's Comirnaty) and modified virus vector vaccine (Janssen's Ad26.COV 2-S).[10] With the emergence of new variants of covid-19, the third dose of vaccine was introduced to the vaccinal program of Moroccan adult individuals to boost the immune system.[11] Policymakers considered the use of a fourth vaccine dose (covid-19 booster) to the high-risk persons (those who were aged above 60 years or who had an immune deficiency).[12]

As the covid-19 vaccination program have been rolled out worldwide, mortality and severe outcomes of covid-19 had been notably reduced. However, it is concerning to note occasional cases of musculoskeletal side effects, including new-onset arthritis, rheumatic diseases, joint disease flare-up, and bursitis.[1,8,9,13,14] Thus, questions were raised about the safety of covid-19 vaccines, particularly in light of the vaccine's potential link to the emergence of autoimmune disorders.[15] While the pathophysiology of these events remained not entirely understood.[1] Hypotheses include multifactorial phenomenon related to genetic risk factors, environmental factors and overstimulation of the immune response.[9] Molecular mimicry (antigen-specific), the most common theory, leading to cross-reaction of immune response between pathogens' antigen in the vaccines and the tissue or organic molecular structures in vivo, can activate overwhelming systemic or local inflammation.[3,9] It is the same mechanism of developing autoimmune diseases through triggering the autoimmune process by virus. It is attributed to the cross-reactivity that results from a lack of tolerogenic effect.[15]

The emerging reports of post vaccinal reactions and the lack of information regarding the possible deterioration of the existing rheumatic disease revealed concerns over long-term vaccine safety and potentially contribute to persisting vaccine hesitancy among patients, especially in patients with AIIRD. Analogously to the literature[16], Fear of vaccine's side effects had been a major barrier for discontinuing the vaccination protocol in both patients with and without AIIRD.[13,14]

AstraZenica, as the most frequently administered vaccine type contributing to related vaccine musculoskeletal reactions, was similar to a recent systematic review.[3] Arthralgia emerged as a common adverse event of vaccines in our study with a notably elevated percentage of remission observed within few days. The reported prevalence was 0.83–46.4% in the general population.[2] Patients with AIIRD, more concerned about arthralgia, may experience more frequent and longer-lasting arthralgia than healthy individuals.[2] Reported cases were split equally among monoarticular and polyarticular arthritis. The knee and the hand were the most affected joints.[8]

The majority of patients with newly developed musculoskeletal symptoms were documented within a week of getting the second dose of the covid-19 vaccine.[8] The new-onset of rheumatic immune-mediated inflammatory diseases, notably RA, following covid-19 vaccination was recorded in 7.7% of a recent systematic review.[17] The majority (80%) of RA patients had polyarthritis presentation.

Individuals with AIIRD, including RA and SpA, and those treated with medications that modulate the immune system were particularly vulnerable to severe covid-19 outcomes. Thus, international and national rheumatology societies.[18,19] recommend covid-19 vaccination for all patients with AIIRD. Whether covid-19 vaccine worsened diseases remain controversial with only a few large-scale studies analyzing the safety of vaccines in this group.[2,13] The literature reports controversial results. According to Pinte et al.[20], patients with autoimmune diseases were not more likely to experience a post-vaccinal flare than unvaccinated patients. Several studies reported no association between covid-19 and RA flare-ups.[20,21] Additionally, no increase in the flare rates and distribution of categorized disease activity followed covid-19 vaccination was noted in patients with RA and psoriatic arthritis on targeted therapy in the COVIDSER study.[14] Conversely, there were anecdotal reports suggesting an association between covid-19 vaccination and the aggravation or a new onset of immune and inflammatory disorders.[14] As program vaccine has progressed worldwide, approximatively 10-13% of patients with rheumatic diseases had reported exacerbation of their subjective symptoms.[22] Takatani et al.[2] suggested that covid-19 vaccine might act as potential trigger for increased disease activity by exacerbating of arthritis in some RA patients and proposed additional csDMARDs post-vaccination to manage the flare-ups within the following 6 months. Flares are often mild or moderate and hospitalization was rare.[16] In our study 4 (4%) of RA and SpA patients developed post vaccinal flare-up and none of them required additional DMARDs treatment. This low rate of flares was in accordance with the various studies ranging from no flares to up to 18%.[23–25]

According to the physician-reported registry for the EULAR coronavirus vaccination, the likelihood of disease recurrences is likely consistent with the diseases' normal course.

The EULAR coronavirus vaccine physician-reported registry suggested that the risk of disease relapses is likely consistent with the diseases' normal course.[21] Additionally, the low rate of RA flares could be related to the predominance of remission or low disease activity before the covid-19 vaccine.[16,26] Indeed, vaccine safety

in patients with rheumatic disease was based on vaccine studies conducted in patients with quiescent disease and suboptimal disease control at the time of covid-19 vaccine.[25,27] At the first covid-19 vaccine dose, all patients were in remission.

Regarding factors associated with the onset of musculoskeletal reactions, our study found two factors positively associated: pre-existing RA and SpA disease and antecedent of covid-19 infection. Pre-existing autoimmunity was found to be a potential risk factor for new-onset post vaccination systemic autoimmune diseases (SAID). This possibly could be attributed to the overactivity of the interferon axis or activation of other immune pathways, predisposing individuals with pre-existing or family history of SAIDs to develop other SAIDs.[28] There is growing evidence that covid-19 infection may promote the development of autoimmune phenomena due to the dysregulation of the immune system. Arthritis and vasculitis were the most reported new-onset AIIRD during or after SARS-cov-2 infection.[29]

Our study is the first to conduct an up-to-date of all reported musculoskeletal reactions related to covid-19 vaccine in patients with AIIRD and group-control without AIIRD in real-world conditions. However, some limitations must be mentioned. Firstly, the retrospective cross-sectional design of the study has its limitations such as recall and risk of reporting bias. Similarly, musculoskeletal reactions were only considered if reported to, and documented in the medical record. Large prospective studies of sufficient sample size with case-control (unvaccinated subjects) are required to validate our results.

CONCLUSION

Our study reported a low occurrence of new-onset musculoskeletal reactions post covid-19 vaccines. Arthralgia was the most common reported reaction.

Our results highlighted the importance of considering the musculoskeletal manifestations following covid-19 vaccination and provided information on risk factors for post covid-19 condition that might help to inform local guidelines. However, the benefits of complete vaccinations still substantially outweigh the potential risks and should be positively encouraged even in patients with underlying AIIRD.

Conflict of interest statement: None.

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