



Frozen shoulder after COVID-19 vaccination versus idiopathic frozen shoulder: similar clinical features and functional improvement at 1-year follow-up

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Background: Frozen shoulder after COVID-19 vaccination is sparsely discussed in the medical literature. We aimed to evaluate: (1) the differences in the baseline clinical features and functional outcomes of conservatively treated frozen shoulder following COVID-19 vaccination compared to idiopathic frozen shoulder (2) the improvements in pain scores, functional outcomes, and range of motion (ROM) at 6–10 months and at 1 year of follow-up in patients with frozen shoulder after COVID-19 vaccination treated by conservative therapy.

Methods: Between June 2021 and December 2021, 12 patients (13 shoulders) that were diagnosed with frozen shoulder after COVID-19 vaccination (vaccine related frozen shoulder [VRF] group) (final follow-up of 12.4 months $\pm$ 0.8 months) were compared with 20 patients that were diagnosed as idiopathic frozen shoulder unrelated to vaccination (unvaccinated frozen shoulder [UFS] group) (average follow-up of 13.4 $\pm$ 3.1 months). All patients were treated with home-based stretching exercises. Four (33%) patients in the VRF group and 15 (75%) patients in the UFS group underwent steroid injection in the suprascapular notch by an experienced radiologist.

Results: The left side was affected more frequently in the VRF group [$n = 10$ (83.3%)] than in the UFS group [$n = 8$ (40%), $P = .03$]. The VRF and the UFS groups were similar in the rest of the baseline clinical features, such as the age distribution, men/women ratio, baseline Oxford Shoulder Scores (OSS), ROM deficit, and pain visual analogue scale (VAS) scores. The OSS, VAS pain scores, and the ROM deficit significantly improved in the VRF group at the 6–10-month follow-up and then at the final (12.4 $\pm$ 0.8 months) follow-up compared to the baseline values. At the final follow-up, there were no significant differences in the average external rotation, external rotation deficit, elevation, elevation deficit, internal rotation, pain VAS scores, and OSS between the VRF and the UFS group.

Conclusion: To conclude, frozen shoulder following COVID-19 vaccination may present with clinical features similar to those of the idiopathic frozen shoulder. Furthermore, the patients with frozen shoulder following COVID-19 vaccination may continue to improve over one year with conservative treatment; the final improvements in function and ROM are similar to those with idiopathic frozen shoulder.

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Vaccination against COVID-19 has proven its efficacy against the novel coronavirus strain 2 and remains one of the most effective strategy in combating the COVID-19 pandemic.²⁶ Shoulder injury after vaccine administration (SIRVA) has been defined as persistent shoulder pain after vaccination that may be caused due to subacromial-subdeltoid bursitis, teres minor injury, axillary nerve

injury, or frozen shoulder.^{1,16} However, frozen shoulder after vaccination has been sparsely reported in the medical literature.²⁷ The orthopedic literature is also virtually devoid of any discussion or data on the occurrence and follow-up of frozen shoulder after COVID-19 vaccination. Furthermore, a diagnosis of frozen shoulder in relation to the COVID-19 vaccination is a source of disbelief and controversy in many physicians' minds,²³ because vaccination as a factor in the development of frozen shoulder has not yet been elucidated.

Our earlier published report described the presenting features in 10 patients with frozen shoulder after COVID-19 vaccination, but no follow-up evaluation was available.²⁵ Because of an absence of published data, we were unsure whether the patients diagnosed with frozen shoulder after COVID-19 vaccination were cases of temporary painful stiffness that would recover in a short duration like the published cases of SIRVA, or they were similar to cases of idiopathic frozen shoulder that will have a protracted 1-year period of recovery. We also did not know whether these cases would have an even more protracted (>1-2 years) recovery period because of the possible severity of the inflammatory response to the vaccine antigen. It is unknown if the presenting clinical features, final recovery, and outcomes are similar or different to that of idiopathic frozen shoulder unrelated to vaccination. Therefore, we aimed to evaluate: (1) the differences in the baseline clinical features and functional outcomes of conservatively treated frozen shoulder following COVID-19 vaccination compared to idiopathic frozen shoulder (2) the improvements in pain scores, functional outcomes, and range of motion (ROM) at 6-10 months and at 1 year of follow-up in patients with frozen shoulder after COVID-19 vaccination treated by conservative therapy.

Material and methods

Study design and setting

The data for the study are drawn from a larger, long-term prospective observational study on the conservative treatment of frozen shoulder; the prospective study was already approved by the Institutional ethics committee before its commencement. All patients were from a single shoulder surgeon's (DS) practice center.

Patients and participants

The study includes all consecutive patients diagnosed with frozen shoulder following the COVID-19 vaccine (Vaccine related frozen shoulder or VRF group) and patients diagnosed as idiopathic frozen shoulder unrelated to vaccination (unvaccinated frozen shoulder or UFS group) between June 2021 and December 2021. The patients in the UFS group had no history of vaccination; hence the symptoms were considered unrelated to vaccination. Frozen shoulder was diagnosed clinically by the senior author (DS) according to the published criteria.²⁵ (1) active and passive restriction of shoulder ROM in at least two planes with an external restriction to less than 50% of the opposite normal limb (as per frozen shoulder trial multicenter study criteria²¹) or <40° in case of bilateral involvement, (2) normal radiographs of the shoulder, (3) symptoms persisting for more than a month and (4) absence of a significant preceding trauma / secondary cause. The exclusion criteria were (1) the presence of significant shoulder pain before the vaccination, (2) symptoms developing after a trauma, shoulder surgery, or surgery on other parts of the body. All patients who presented with a diagnosis of frozen shoulder (based on the above criteria) following the COVID-19 vaccination were classified as frozen shoulder

following the COVID-19 vaccine. Between June 1, 2021, and December 31, 2021, 16 shoulders in 14 patients (two with bilateral affection and 12 with unilateral affection) were diagnosed as frozen shoulder after COVID-19 vaccination. Two patients (one with bilateral affection and one with unilateral affection) refused to return for a follow-up, and 13 shoulders in 12 patients (one patient had bilateral affection) were included with a final mean follow-up of 12.4 months $\pm$ 0.8 months (VRF group). In the same study period, 25 patients were diagnosed with idiopathic frozen shoulder, 5 were lost to follow-up, and finally, 20 shoulders in 20 patients were evaluated at an average follow-up of 13.4 $\pm$ 3 months (UFS group).

Interventions

All patients in both groups were treated with home-based 4-way stretching exercises as per our published regimen.²⁴ All patients were also offered to undergo a steroid injection (2 milliliters of 80-milligram injection triamcinolone mixed with 6 milliliters of injection 0.5% bupivacaine) in the suprascapular nerve notch (SSN) under ultrasonography by an experienced radiologist. SSN injections and not intraarticular injections were offered to the patients because SSN injections were part of the prospective study protocol as the prevailing protocol of our unit for treating frozen shoulders at the time.

Outcome variables

Baseline variables that were collected for both groups included: age, gender, dominant side, presence of comorbidities, Visual Analogue scale (VAS) scores for pain, Oxford Shoulder Scores (OSS), ROM for both shoulders, and deficit in ROM (as compared to opposite normal side in $n = 11$ patients in VRF group). The OSS is a validated, shoulder-specific, 12-item patient-reported-outcome score; an OSS of 0 points represents the poorest outcome, and an OSS of 48 points represents the best outcome. Additional data collected for the VRF group included: the type of vaccine and the time duration between the vaccination and the onset of symptoms. A history of vaccination (COVID-19 or any other vaccine) was also sought from all patients in the UFS group. Outcome variables that were collected included VAS scores for pain, OSS, and ROM. An independent research assistant recorded the following ROM measurements: elevation and external rotation (with elbow adducted by the side of the body) using a goniometer and internal rotation by the extended thumb reaching the highest vertebrae at the back. ROM variables were recorded for both shoulders. These variables were collected at presentation, 6-10 months, and finally at 12-15 months follow-up in the VRF group. In the UFS group, the variables were available for evaluation at the baseline and then at the final follow-up.

Statistical analysis

SPSS version 26.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. We compared the baseline and outcome variables between the VRF and the UFS groups. In the VRF group, the outcome variables were also compared between the baseline and the 6-10-month follow-up period, between the 6-10 month and the final 1-year follow-up period, and between the baseline and the 1-year follow-up period.

Continuous variables were expressed as mean $\pm$ standard deviation and compared using paired or unpaired t-tests as appropriate. Categorical variables were expressed as percentages and compared using chi-square or Fisher's exact test (for $n < 5$). P value < .05 was considered significant.

Table I

Baseline clinical features of patients who presented with a diagnosis of frozen shoulder after vaccination (VRF group).

Variable	
Age in years, mean (SD)	53 (7)
Female, n (%)	10 (83.3%)
Side affected (left / right), n (%)	11 (85%) / 2 (15%)
Dominant right side, n (%)	12 (100%)
Patients with comorbidities, n (%)	10* (83.3%)
Type of vaccine, n (%)	Covishield, 11 (92%); Covaxin, 1 (8%),
Onset of symptoms after vaccination, n (%)	
Immediate	7 (58%)
Within 24 h	1 (8%)
Within 48 h	2 (17%)
10 days	1 (8%)
21 days	1 (8%)
Duration of symptoms (weeks), n (SD)	17 (10)
Pain VAS score, mean (SD)	7 (1.4)
Oxford shoulder scores, mean (SD)	22 (4)
Deficit in elevation (°), mean (SD)	65 (25)
External rotation (°), mean (SD)	30 (14)
Deficit in external rotation (°), mean (SD)	47 (11)
Internal rotation (vertebral level), mean (SD)	[†] L4 (2)
Deficit in internal rotation (vertebrae), mean (SD)	8 [‡] (3.6)

VAS, visual analogue scale; SD, standard deviation.

*10 patients with comorbidities included: diabetes mellitus (n = 6), thyroid disorder (n = 4).

[†]Lumbar vertebrae.

[‡]Vertebrae.

Results

Baseline clinical features of frozen shoulder following COVID-19 vaccination compared to idiopathic frozen shoulder

The same side [left side (n = 10), right side (n = 1)] as the vaccination side was affected in 11 patients in the VRF group (Table I); both sides were affected in one patient after the vaccine was taken on the left side. The left side was affected more frequently in the VRF group [n = 10 (83.3%)] than in the UFS group [n = 8 (40%), $P = .03$] (Table II). Eleven (92%) patients (Table I) developed frozen shoulder after the Covishield® vaccine (non-replicating viral vector type vaccine, Serum Institute of India/AstraZeneca, Pune, India)[17], and 1 (8%) patient developed frozen shoulder after the Covaxin® vaccine (inactivated whole virus vaccine, Bharat Biotech International Limited, Telangana, India).¹⁹ The onset of symptoms after the vaccination was immediate [n = 7(58%)], within 24 hours [n = 1(8%)], within 48 hours [n = 2 (17%)]; 2 patients reported persistent soreness in the shoulder immediately, and the pain increased within 10 days [n = 1 (8%)] or within 21 days [n = 1(8%)]. None of the patients in the UFS group had received any vaccination (COVID-19, Influenza, or Tetanus). The frequency of the presence of the comorbidities was not significantly different between the VRF [10 (83.3%)] and the UFS group [11 (55%), $P = .1$]. The VRF and the UFS groups were similar regarding the baseline clinical features (except for the side of involvement), such as the age distribution, men/women ratio, final follow-up duration baseline Oxford scores, ROM deficit, and pain VAS scores (Tables II and III). Four (33%) patients in the VRF group and 15 (75%) patients in the UFS group agreed and underwent the SSN steroid injection under ultrasonography by an experienced radiologist ($P = .02$) (Table II).

Improvements in pain scores, functional outcomes, and range of motion at 6-10 months and at 1 year of follow-up in patients with frozen shoulder after COVID-19 vaccination treated by conservative therapy, and the differences in the final outcomes compared to that of the idiopathic frozen shoulder unrelated to vaccination

All ROM variables significantly improved from baseline to 6-10-month follow-up and then from 6-10 months to the final follow-up in the VRF group (Fig. 1 A and B) (Table IV). The OSS and VAS pain scores improved significantly at the 6-10-month follow-up and then at the final (12.4 ± 0.8 months) follow-up as compared to the baseline values in the VRF group (Fig. 1 C and D) (Table IV).

At the final follow-up (12.4 ± 0.8 months in VRF and 13.4 ± 3.1 months in UFS group), there were no significant differences in the external rotation, external rotation deficit, elevation, elevation deficit, internal rotation, VAS pain scores, and OSS between the VRF and the UFS group (Table III) (Fig. 2 A-E). The final pain VAS score and the OSS were 2 ± 2.5 and 37 ± 10 in the VRF group and 2 ± 2.2 and 40 ± 8 in the UFS group (Table III). The VAS pain scores, ROM and OSS, did not improve at 1-year follow-up in one patient (both shoulders) in the VRF group. This patient, with bilateral affection, had also refused the shoulder steroid injection. Three additional patients in the VRF group had OSS below 40 but a pain VAS scores ≤ 1, indicating ongoing symptoms mainly due to ROM restrictions at 1-year follow-up.

Discussion

Currently, there is an absence of knowledge about whether the frozen shoulder after COVID-19 vaccination are cases of painful stiffness that will recover in a few weeks or whether these cases may have a protracted recovery period similar to or even more prolonged than the idiopathic frozen shoulder unrelated to vaccination.

Our study found that the baseline clinical features of the patients with frozen shoulder following COVID-19 vaccination, such as age, sex, pain VAS scores, ROM limitation, and functional (OSS) scores, were similar to those with the unvaccinated idiopathic frozen shoulder. Both shoulders were affected in one patient after vaccination was performed in the left arm, but in the rest of the patients, the affected shoulder was the side (left, n = 10 and right, n = 1) that received the vaccination. Notably, the left side was involved more frequently in the VRF group than in the UFS group; this may have occurred because the left arm was the preferred vaccination arm in most cases. Although the frequency of comorbidities was higher in the VRF group than in the UFS group (83.3% versus 55%), this difference was not statistically significant. In our study, frozen shoulder developed after Covishield® vaccine, which is a nonreplicating adenoviral vector vaccine (ChAdOx1nCoV-19) (produced by Serum Institute of India in collaboration with AstraZeneca)¹⁰ in 11 (92%) patients and after Covaxin®, which is an inactivated viral vaccine (BBV152) (developed by Bharat Biotech)¹⁰ in 1 (8%) patient. However, we are unable to link the development of the frozen shoulder with a particular type of vaccine because the Covishield vaccine has been used in the majority of the population in our country. The most common vaccines used in the United States are the mRNA-based vaccines [Pfizer/BioNTech vaccine (BNT162b2), Pfizer, New York, NY, USA; and the Moderna vaccine (mRNA-1273); Moderna, Cambridge, MA, USA].¹⁰

We also found that the functional outcomes and the ROM in the VRF group continuously improved until the 1-year follow-up. The outcomes after 1-year of conservative treatment were similar to that of the idiopathic frozen shoulder group in our study. The

Table II

Baseline clinical features of patients who presented with a diagnosis of frozen shoulder after vaccination (VRF) and unvaccinated frozen shoulder (UFS).

Variable	UFS group (n = 20)	VRF group (n = 12)	P value
Age in years, mean (SD)	56 (8)	53 (7)	.3
Male/female, n (%)	8 (40%) / 12 (60%)	2 (16.7%) / 10 (83.3%)	.2
Side affected: right/left, n (%)	12 (60%) / 8 (40%)	1 (8.3%) / 10 (83.3%); 1 Bilateral (8.3%)	.03*
Dominant right side, n (%)	19 (95%)	12 (100%)	1
Patients with comorbidities, n (%)	11 [†] (55%)	10 [†] (83.3%)	.1
Pain VAS score, mean (SD)	7 (1.7)	7 (1.4)	.99
Oxford scores, mean (SD)	18 (8)	22 (4)	.1
Deficit in elevation (°), mean (SD)	62 (28)	65 (25)	.81
External rotation (°), mean (SD)	30 (14)	17 (2)	.99
Deficit in external rotation (°), mean (SD)	43 (20)	47 (11)	.57
Internal rotation (vertebral level), mean (SD)	L5 [‡] (2)	L4 (2)	.74
Deficit in internal rotation (vertebrae), mean (SD)	9 [§] (3)	8 [§] (4)	.24
No. of patients who underwent steroid shoulder injection, n (%)	15 (75%)	4 (33%)	.02*

VAS, visual analogue scale; SD, standard deviation.

10 patients with comorbidities in VRF group included: Diabetes (n = 6), Thyroid disorder (n = 4).

*P < .05 represents significant difference.

[†]11 patients with comorbidities in UFS group included: diabetes (n = 10), thyroid disorder (n = 1) diagnosis with unvaccinated frozen shoulder.[‡]Lumbar vertebrae.[§]Vertebrae.**Table III**

Comparison of final outcomes between the frozen shoulder after vaccination (VRF) group and unvaccinated frozen shoulder (UFS) group.

Variable	UFS group	VRF group	P value
Pain VAS score, mean (SD)	2 (2.2)	2 (2.5)	.7
Elevation (°), mean (SD)	131(20)	131 (14)	.9
Deficit in elevation (°), mean (SD)	26 (28)	16 (17)	.3
External rotation (°), mean (SD)	49 (20)	53 (13)	.5
Deficit in external rotation (°), mean (SD)	17 (19)	15 (8)	.8
Internal rotation (vertebral level), mean (SD)	T12 [†] (4)	T11 [†] (4)	.4
Deficit in internal rotation (vertebrae), mean (SD)	5 [‡] (3)	2 [‡] (2)	.003*
Oxford score, mean (SD)	40 (8)	37 (10)	.4
Follow-up duration in months, mean (SD)	13.4 (3.1)	12.4 (0.8)	.31

VAS, visual analogue scale; SD, standard deviation.

*Significant difference with P < .05.

[†]Thoracic vertebrae.[‡]Vertebrae.

largest multicenter prospective trial on frozen shoulder reported that functional improvement of the patients may continue up to 1 year or more with conservative or surgical therapy, but most of the patients resolve by one year. In our study, only one patient's symptoms in the VRF group remained the same and did not improve at all at 1-year follow-up. This patient had an affection of both shoulders simultaneously. It is uncommon for both shoulders to develop frozen shoulder simultaneously; this may also represent severe affection of the disease. Reports indicate that patients with severe symptoms at presentation may take more than 1–3 years to recover.^{12,13} Three other patients had ongoing mild painless ROM restrictions and OSS below 40 at 1-year that indicated need for further supervision and improvement. This is in agreement with earlier long-term studies on frozen shoulder that indicate mild to moderate symptoms may continue in 15–30% of patients after 1 year.^{13,21}

The findings of our study are significant because painful stiffness after vaccination may be due to frozen shoulder and may need to be treated and counseled appropriately for the protracted 1-year recovery period. There is widespread disbelief about the presence of the entity (frozen shoulder after COVID vaccination),²³ partly because of no prior data on the topic and partly due to the poorly understood rationale behind frozen shoulder after vaccination; hence treating physicians may not pay adequate attention to the

problem²³ and length of recovery that the patients may have to endure. Moreover, to the best of our knowledge, there are no clinical follow-up studies on frozen shoulder after any type of vaccination in the scientific literature. Few studies in non-orthopedic journals have mentioned that “painful stiffness” may occur after influenza or tetanus vaccine, and the symptoms may take a few months to recover^{1,14}; it is possible that some of the patients with the aforementioned “painful stiffness” could have been cases of frozen shoulder if objective follow-up had been reported. Subacromial bursitis following the COVID-19 vaccine has been reported in numerous case reports,^{4,7,8} but adhesive capsulitis after the COVID-19 vaccine has been reported in one case report without a follow-up or description of the symptoms.³ A recent case series with a 2-month follow-up described 9 patients who developed symptoms of frozen shoulder after the Covishield vaccine.¹¹ However, an important distinction is that all patients significantly resolved within two months in their series. Thus, their series likely consisted of patients with painful stiffness with a short recovery period who may not have had frozen shoulder; it typically takes around a year or sometimes more than a year for frozen shoulder to resolve.^{12,21} An earlier case report described 3 cases of adhesive capsulitis following tetanus, hepatitis, and influenza vaccine, but the authors did not objectively report the follow-up and resolution of the problem beyond 1–3 months.⁹

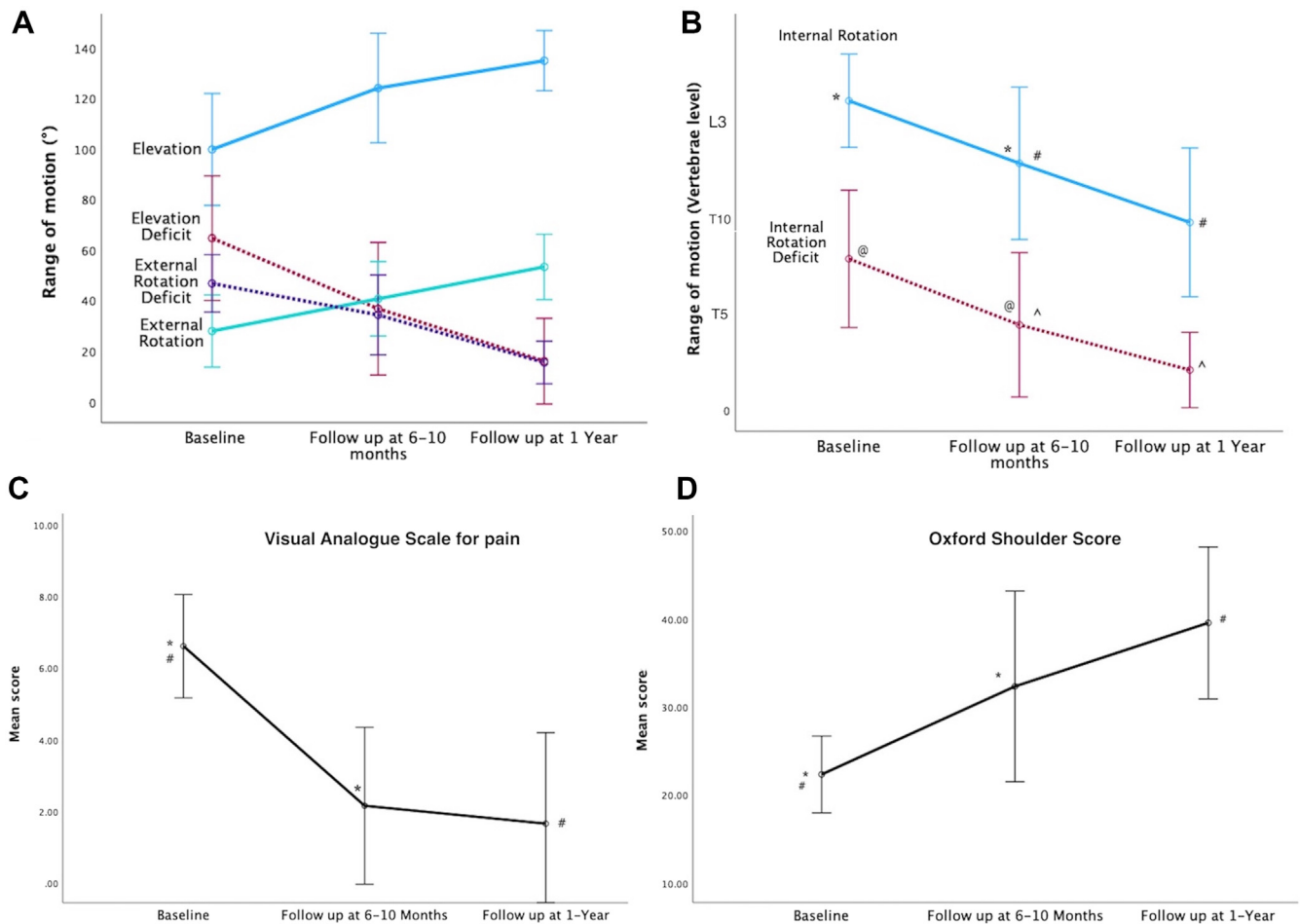


Fig. 1 (A-D) Vaccine related frozen shoulder group (VRF group)- the line diagram shows. **(A)** Significant improvements in elevation, elevation deficit, external rotation, and external rotation deficit between baseline and 6-10 months of follow-up, between 6-10-months and 12 months of follow-up, and between baseline and 12 months of follow-up. **(B)** Significant improvements in internal rotation and internal rotation deficit between baseline and 6-10 months of follow-up, between 6-10-month and 12-month follow-up, and between baseline and 12-month follow-up. [*, #, ^, @ indicates a significant difference (<0.05) between the denoted observations]. **(C)** Significant improvements in VAS pain scores between baseline and 6-10 months of follow-up and between baseline and 12 months of follow-up. [*, # indicates a significant difference (<0.05) between the denoted observations]. **(D)** Significant improvements in Oxford Shoulder Score (OSS) between baseline and 6-10 months of follow-up and between baseline and 12 months of follow-up. [*, # indicates a significant difference (<0.05) between the denoted observations]. VAS, visual analogue scale.

Table IV

Baseline features and follow-up of patients who presented with a diagnosis of frozen shoulder after vaccination (VRF).

Variable	Baseline	6-10 mo follow-up	1 y follow-up	Comparison between baseline & 6-10 mo (P value)	Comparison between 6-10 mo & 1 y (P value)	Comparison between baseline & 1 y (P value)
Pain VAS score, mean (SD)	7 (1)	2 (2)	2 (2.5)	<.001*	.2	<.001*
Elevation (°), mean (SD)	103 (22)	122 (20)	131 (14)	.03*	.04*	.001*
Deficit in elevation (°), mean (SD)	65 (25)	37 (26)	16 (17)	.01*	.002*	<.001*
External rotation (°), mean (SD)	30 (14)	41 (14)	53 (13)	.004*	.003*	<.001*
Deficit in external rotation (°), mean (SD)	47 (11)	34 (16)	15 (8)	.01*	.01*	<.001*
Internal rotation (vertebral level), mean (SD)	L4 [†] (2)	L2 [‡] (4)	T11 [§] (4)	.01*	<.001*	<.001*
Deficit in internal rotation (vertebrae), mean (SD)	8 [§] (4)	4 [§] (4)	2 [§] (2)	.01*	.01*	<.001*
Oxford shoulder score, mean (SD)	22 (4)	32 (10)	37 (10)	.003*	.15	<.001*

VAS, visual analogue scale; SD, standard deviation.

*Significant difference ($P < .05$).

[†]Lumbar vertebrae.

[‡]Thoracic vertebrae.

[§]Vertebrae.

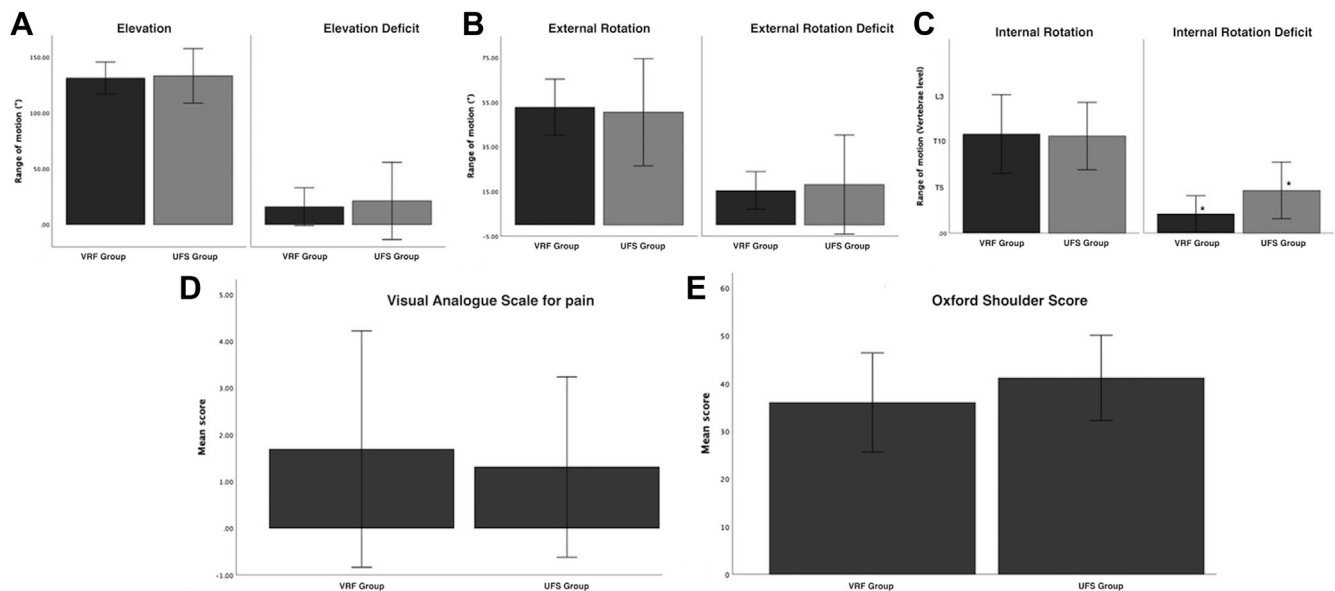


Fig. 2 (A-E) Bar graph compares the unvaccinated Frozen shoulder (UFS) and the vaccine related frozen shoulder (VRF) groups at their final follow-ups and shows: (A) No significant differences in the elevation and elevation deficit. (B) No significant differences in the external rotation and external rotation deficit. (C) No significant difference in internal rotation but a small significant difference in internal rotation deficit [* indicates significant difference (<0.05) between the denoted observations]. (D) No significant difference in the Visual Analogue Scale (VAS) pain scores. (E) No significant difference in the Oxford Shoulder Score (OSS).

The term SIRVA or a shoulder injury related to vaccine administration has been used in the medicolegal domain for compensation of the affected subjects; hence the true clinical resolution of the problem has not been elucidated. Our study had no patients seeking any medicolegal compensation, but all the patients were from an orthopedic surgeon's practice center.

Home-based stretching exercises have led to satisfactory outcomes in the treatment of frozen shoulder.¹² The largest multicenter prospective trial on frozen shoulder reported that conservative therapy and surgical therapies such as arthroscopy release and manipulation under general anesthesia are effective to a similar extent, but conservative therapy has a lower incidence of serious side effects.²¹ Therefore, conservative treatment that consists of home-based stretching exercises and a steroid injection is our standard treatment regimen for all frozen shoulder patients. However, significantly fewer patients underwent the steroid injection in the VRF group than in the UFS group. Some patients were apprehensive about accepting another needle/injection in the shoulder because, in their minds, a recent needle of the vaccine was the reason behind their malady. We used steroid injections in the SSN notch and not in the intraarticular location because of the prevailing protocol of a long-term frozen shoulder study at the time, as the current study's data is part of a prospective long-term study on frozen shoulder. The SSN notch steroid injections have been commonly used in the treatment of frozen shoulder¹⁵ and have been found to be as effective as intraarticular steroid injections in a recent trial.¹⁷ Notably, steroid injections have been known to be effective only in the first few weeks and do not change the long-term outcomes of frozen shoulder.^{2,20,22}

In our earlier report, we had speculated that the frozen shoulder in vaccination cases may have occurred due to the antigen being transported locally to the capsular structures and the nerves via the local lymphatic channels; and the presence of prior antibodies may have given rise to an antigen-antibody reaction, thus leading to a development of frozen shoulder.²⁵ In earlier reports, an immunological basis has been found to be an etiological factor for the

development of idiopathic frozen shoulder.^{5,6} However, the true reason for idiopathic frozen shoulder, regardless of the etiological factor, has not been well elucidated. Thus, the occurrence of frozen shoulder after vaccination may only have speculative reasoning. Similarly, the true cause behind other idiopathic occurrences after vaccination, such as Guillain Barre syndrome and thrombocytopenic purpura, is unknown but has been theorized to occur due to transfection of the viral antigen and a resultant autoimmune reaction to nerves and platelets.¹⁸

Limitations

Our study has several limitations. We report only a small number of patients with frozen shoulder after COVID-19 vaccine diagnosis with a 1-year follow-up because frozen shoulder after vaccination is a rare problem. The presentation of the problem has only recently increased because our country has undergone the largest vaccination drive in the world, with more than 2 billion doses of vaccines against COVID-19 administered to date.¹⁹ We did not perform a sample size calculation because frozen shoulder following the COVID-19 vaccine is a rare problem, and we included all patients that presented to us. Although higher numbers are desirable for statistical relevance, the rare nature of the problem may make it extremely challenging to increase the number of patients. Additionally, 1 year was considered an adequate follow-up duration because the majority of the patients in both groups had resolved to a large extent. We only report that the frozen shoulder occurred following the COVID-19 vaccination, but no firm conclusions can be drawn about whether the vaccination truly caused the problem; hence the post hoc ergo propter hoc fallacy should be kept in mind. The groups differed in the number of patients who received the steroid injections, but it is widely believed that steroid injections are only effective in short-term (first 3 months) and do not affect the outcomes at 1 year in the treatment of frozen shoulder; hence the final outcomes were not likely influenced by the different number of steroid injections in the groups in our study.

Conclusions

Frozen shoulder following COVID-19 vaccination may present with clinical features similar to those of the idiopathic frozen shoulder unrelated to vaccination. Furthermore, the patients with frozen shoulder following COVID-19 vaccination may continue to improve over one year with conservative treatment; the final improvements in function and ROM were similar to those with idiopathic frozen shoulder. Therefore, the treating physicians may need to pay adequate attention to patients presenting with frozen shoulder after COVID-19 vaccination and counsel the patients regarding the length of recovery (6–12 months) that the patients may have to endure with conservative therapy.

Declarations:

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References

- Atanasoff S, Ryan T, Lightfoot R, Johann-Liang R. Shoulder injury related to vaccine administration (SIRVA). *Vaccine* 2010;28:8049–52. <https://doi.org/10.1016/j.vaccine.2010.10.005>.
- Bal A, Eksioğlu E, Gulec B, Aydog E, Gurcay E, Cakci A. Effectiveness of corticosteroid injection in adhesive capsulitis. *Clin Rehabil* 2008;22:503–12. <https://doi.org/10.1177/0269215508086179>.
- Biglia A, Morandi V, Zanframundo G, Donati D, Maggiore F, Vita F, et al. Adhesive capsulitis after COVID-19 vaccine injection: a peculiar case treated with combined bursa distention and glenohumeral capsular hydrodilatation. *J Ultrasound* 2023;(0123456789):6–8. <https://doi.org/10.1007/s40477-022-00739-3>.
- Boonsri P, Chuaychoosakoon C. Combined subacromial-subdeltoid bursitis and supraspinatus tear following a COVID-19 vaccination: a case report. *Ann Med Surg* 2021;69:102819. <https://doi.org/10.1016/j.amsu.2021.102819>.
- Bulgen DY, Binder A, Hazleman BL, Park JR. Immunological studies in frozen shoulder. *J Rheumatol* 1982;9:893–8.
- Bulgen DY, Hazleman BL, Ward M, McCallum M. Immunological studies in frozen shoulder. *Ann Rheum Dis* 1978;37:135–8.
- Cantarelli Rodrigues T, Hidalgo PF, Skaf AY, Serfaty A. Subacromial-subdeltoid bursitis following COVID-19 vaccination: a case of shoulder injury related to vaccine administration (SIRVA). *Skeletal Radiol* 2021;50:2293–7. <https://doi.org/10.1007/s00256-021-03803-x>.
- Chuaychoosakoon C, Parinyakhup W, Tanutit P, Maliwankul K, Klabklay P. Shoulder injury related to Sinovac COVID-19 vaccine: a case report. *Ann Med Surg* 2021;68:102622. <https://doi.org/10.1016/j.amsu.2021.102622>.
- Degreef I, Debeer P. Post-vaccination frozen shoulder syndrome. report of 3 cases. *Acta Chir Belg* 2012;112:447–9. <https://doi.org/10.1080/00015458.2012.11680872>.
- Fathizadeh H, Afshar S, Masoudi MR, Gholizadeh P, Asgharzadeh M, Ganbarov K, et al. SARS-CoV-2 (Covid-19) vaccines structure, mechanisms and effectiveness: a review. *Int J Biol Macromol* 2021;188:740–50. <https://doi.org/10.1016/j.ijbiomac.2021.08.076>.
- Ghosh S, Pandey SK, Biswas A, Pandey J. Adhesive capsulitis after COVID-19 vaccination: a case series. *Am J Phys Med Rehabil* 2023;102:E79–82. <https://doi.org/10.1097/PHM.0000000000002194>.
- GRIGGS SM, AHN A, GREEN A. Idiopathic adhesive capsulitis. *J Bone Jt Surg Am* 2000;82:1398–407.
- Hand C, Clipsham K, Rees JL, Carr AJ. Long-term outcome of frozen shoulder. *J Shoulder Elbow Surg* 2008;17:231–6. <https://doi.org/10.1016/j.jse.2007.05.009>.
- Hesse EM, Atanasoff S, Hibbs BF, Adegoke OJ, Ng C, Marquez P, et al. Shoulder injury related to vaccine administration (SIRVA): petitioner claims to the national vaccine injury compensation program, 2010–2016. *Vaccine* 2020;38:1076–83. <https://doi.org/10.1016/j.vaccine.2019.11.032>.
- Jump CM, Waghmare A, Mati W, Malik RA, Charalambous CP. The impact of suprascapular nerve interventions in patients with frozen shoulder: a systematic review and meta-analysis. *JBJS Rev* 2021;9:1–18. <https://doi.org/10.2106/JBJS.RVW.21.00042>.
- MacMahon A, Nayar SK, Srikumaran U. What do we know about shoulder injury related to vaccine administration? An updated systematic review. *Clin Orthop Relat Res* 2022;Publish Ah:1241–1250. <https://doi.org/10.1097/corr.0000000000002181>.
- Mardani-Kivi M, Nabi BN, Mousavi M-H, Shirangi A, Leili EK, Ghadim-Limudahi ZH. Role of suprascapular nerve block in idiopathic frozen shoulder treatment: a clinical trial survey. *Clin Shoulder Elbow* 2022;25:129–39. <https://doi.org/10.5397/cise.2021.00661>.
- Merchant H. Inadvertent injection of COVID-19 vaccine into deltoid muscle vasculature may result in vaccine distribution to distance tissues and consequent adverse reactions. *Postgrad Med J* 2021;98:e5. <https://doi.org/10.1136/postgradmedj-2021-141119>.
- Ministry of Health and Family Welfare, Government of India. Indian COVID-19 vaccine tracker [Internet]. [cited 2021 Sep 30]; Available from: <https://www.mohfw.gov.in>.
- Oh JH, Oh CH, Choi JA, Kim SH, Kim JH, Yoon JP. Comparison of glenohumeral and subacromial steroid injection in primary frozen shoulder: A prospective, randomized short-term comparison study. *J Shoulder Elbow Surg* 2011. <https://doi.org/10.1016/j.jse.2011.04.029>.
- Rangan A, Brealey SD, Keding A, Corbacho B, Northgraves M, Kottam L, et al. Management of adults with primary frozen shoulder in secondary care (UK FROST): a multicentre, pragmatic, three-arm, superiority randomised clinical trial. *Lancet* 2020;396:977–89. [https://doi.org/10.1016/S0140-6736\(20\)31965-6](https://doi.org/10.1016/S0140-6736(20)31965-6).
- Ryans I, Montgomery A, Galway R, Kernohan WG, McKane R. A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis. *Rheumatology* 2005;44:529–35. <https://doi.org/10.1093/rheumatology/keh535>.
- Sahu D. What's important: the challenge in diagnosing frozen shoulder after COVID-19 vaccination. *J Bone Jt Surg* 2022;104:2127–8. <https://doi.org/10.2106/JBJS.22.00420>.
- Sahu D, Rathod V, Phadnis A, Bansal SS. Telehealth for consultation and shoulder rehabilitation: a preliminary study on the perspectives of 30 patients during the COVID-19 lockdown. *Clin Shoulder Elbow* 2021;24:156–65. <https://doi.org/10.5397/cise.2021.00248>.
- Sahu D, Shetty G. Frozen shoulder after COVID-19 vaccination. *JSES Int* 2022;6:682–5. <https://doi.org/10.1016/j.jseint.2022.02.013>.
- Victora CG, Castro MC, Gurzenda S, Medeiros AC, França GVA, Barros AJD. Estimating the early impact of vaccination against COVID-19 on deaths among elderly people in Brazil: analyses of routinely-collected data on vaccine coverage and mortality. *EClinicalMedicine* 2021;38:101036. <https://doi.org/10.1016/j.eclim.2021.101036>.
- Wiesel BB, Keeling LE. Shoulder injury related to vaccine administration. *J Am Acad Orthop Surg* 2021;29:732–9. <https://doi.org/10.5435/JAAOS-D-21-00021>.