



Frozen shoulder after COVID-19 vaccination

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Background: The data on frozen shoulder and shoulder injury related to vaccine administration (SIRVA) after coronavirus disease 2019 (COVID-19) vaccination are absent from the literature. Hence, the purpose of this case series was to describe the clinical presentation and short-term follow-up of patients who developed frozen shoulder after COVID-19 vaccination.

Methods: In the present study, 10 patients (9 women and 1 man) with a mean age of 53 ± 8 years (range, 43–68 years) who presented to the shoulder surgeon's practice center with painful stiffness of the shoulder after COVID-19 vaccination between June 1 and September 30, 2021, were retrospectively evaluated.

Results: All 10 patients had normal radiographs and were diagnosed as frozen shoulder. Eight patients (80%) had a comorbidity during presentation (4 patients with hypothyroidism, 3 patients with diabetes mellitus, and 1 patient with prediabetes/hyperglycemia). Symptoms developed immediately after the vaccination in 6 patients (60%), at 48 hours in 1 patient (10%), and at 10 days in 3 patients (30%). The mean pain visual analog scale score was 6.5 ± 1.9 (range, 2.5–8), and both active and passive range of motion were limited in all the patients at the time of presentation.

Conclusion: The musculoskeletal specialists who will see such patients with painful shoulder stiffness should be aware of the frozen shoulder diagnosis, which can occur after COVID-19 vaccination, so that such patients can be identified and treated early.

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Vaccination against the coronavirus disease 2019 (COVID-19) has been reported to be an effective countermeasure and may reduce serious illness, hospitalization, and mortality due to COVID-19.¹⁹ Shoulder injury related to vaccine administration or shoulder injury related to vaccine administration (SIRVA) has been defined as any pain and dysfunction of the shoulder occurring within 48 hours of the vaccine administration and lasting for more than 7 days; SIRVA has been earlier reported with influenza and tetanus vaccines.^{1,13} Shoulder injury and the resultant disability due to SIRVA have been a cause for petitioners' claim for compensation, which may increase substantially considering the increasing number of COVID-19 vaccination.²¹ However, the presentation and

prognosis of vaccine-related shoulder dysfunction after COVID-19 vaccination is unclear. Frozen shoulder is a severe shoulder dysfunction that takes more than a year to recover with the correct treatment, and 30%–40% of patients can have persistent mild to moderate symptoms at 2–3 years of follow-up.¹⁰ But, the data and discussion on frozen shoulder after COVID-19 vaccination are virtually absent from the literature.²¹ To date, there have been only 3 cases reports that have reported shoulder pain secondary to subacromial-subdeltoid bursitis after COVID-19 vaccination.^{2,6,7} Hence, the purpose of this case series was to describe the clinical presentation and short-term follow-up of patients who developed frozen shoulder after COVID-19 vaccination.

Material and methods

Here, we present a series of 10 consecutive patients who presented with shoulder pain and stiffness after COVID-19 vaccination to a senior shoulder surgeon's practice center. All the patients were examined by the shoulder surgeon.

This research observational study was conducted retrospectively from data obtained for clinical purposes. The hospital local Research Ethics Committee decided that no ethical approval is required.

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Patients and participants

Twenty-five patients diagnosed as idiopathic frozen shoulder were seen in the shoulder surgeon's practice center between June 1 and September 30, 2021. Ten of these 25 patients developed frozen shoulder after COVID-19 vaccine administration. We retrospectively evaluated these 10 consecutive patients who complained of painful stiffness of the shoulder after COVID-19 vaccination. We excluded those patients who had significant shoulder pain and stiffness before the administration of the first dose of the COVID-19 vaccine. The shoulders in all patients were evaluated clinically for local tenderness, swelling, and shoulder active and passive range of motion (ROM). Standard anteroposterior and lateral radiographs of the affected shoulder were also done in all patients. Magnetic resonance imaging (MRI) was not advised as an investigation, as it does not help in the management.²¹ However, 3 patients already had an MRI with them at the time of initial consultation. Patients were diagnosed as having adhesive capsulitis or frozen shoulder if (1) active and passive ROM were restricted in at least 2 directions and external rotation (with the adducted arm) was restricted to $\leq 50\%$ compared with opposite normal extremity (as per the FROST multicenter study diagnostic criteria¹⁷), (2) a normal shoulder radiograph, (3) pain and stiffness persisting for more than a month, and (4) absence of any apparent trauma or a secondary cause.¹⁴

Interventions

All patients were treated with oral nonsteroidal anti-inflammatory drugs and a standard rehabilitation regimen of home-based shoulder exercises as per the consultant's standard protocol.¹⁸ Steroid injection in the shoulder under ultrasound control as per the existing standard protocol of the hospital was offered to the patient if the pain was not relieved after 1 month of oral nonsteroidal anti-inflammatory drug treatment. Only 2 patients had undergone steroid injection treatment, and the rest of the patients were still undecided.

Outcome variables

Clinical variables recorded in all patients included duration of symptoms, comorbidities, presence of discomfort or mild pain before the vaccination event, the lag period between the development of pain and the vaccination event, type of vaccine, follow-up period, shoulder ROM, and visual analog scale pain scores at baseline and at latest follow-up. Active and passive elevation and external rotation ROM of both shoulders were measured using a goniometer. Internal rotation ROM was measured based on the thumb reaching the highest vertebrae.

Statistical analysis

Data were analyzed using descriptive statistics such as mean \pm standard deviation and range.

Results

Ten patients (9 women and 1 man) with a mean age of 53 ± 8 years (range, 43–68 years) developed painful shoulder stiffness following COVID-19 vaccination. All 10 patients had normal radiographs and were diagnosed as adhesive capsulitis or frozen shoulder. The side of involvement was the same shoulder as the vaccination side in all patients in this series. The 3 patients who presented with an MRI of the shoulder had no abnormal findings on the MRI. Nine patients (90%) received a nonreplicating viral vector type vaccine (Covishield vaccine; Serum Institute of India, India),¹⁶

and 1 patient received an inactivated whole virus vaccine (Covaxin vaccine; Bharat Biotech International Limited, India)¹⁶ (Table I)

Eight patients (80%) had a comorbidity during presentation (4 patients with hypothyroidism, 3 patients with diabetes mellitus, and 1 patient with prediabetes/hyperglycemia; Table I).

Six patients (60%) had no symptoms in their affected shoulder, and 4 (40%) patients had mild, intermittent shoulder pain before the vaccination (Table I). Symptoms developed immediately after the vaccination (within 24 hours) in 6 patients (60%), at 48 hours in one patient (10%), and at 10 days in 3 patients (30%; Table I). One patient had mild pain after the first dose of the vaccine and an aggravated pain and ROM restriction after the second. The mean duration of presentation since the onset of symptoms was 8.4 ± 3.6 weeks (range, 6–18 weeks). The mean visual analog scale score was 6.5 ± 1.9 (range, 2.5–8), and both active and passive ROM were limited in all the patients at the time of presentation (Table II). At presentation, the mean active shoulder elevation ROM was $103^\circ \pm 23.5^\circ$ (range, 68° – 135°), and the mean active shoulder external rotation ROM was $29^\circ \pm 9^\circ$ (range, 15° – 45°).

Nine patients were available for follow-up, and one was lost to follow-up. At a mean follow-up of 1.4 months (range, 0.5–2.5 months), 3 (33%) patients had 20% resolution, and 6 (67%) patients had no improvement in shoulder ROM (Table II). Pain improved 90% and 70% in 2 patients, who had undergone shoulder steroid injection.

Discussion

Most patients with SIRVA seek treatment from musculoskeletal specialists.²¹ Hence, a clinical description and data regarding shoulder injury after the COVID-19 vaccine is important for the education and awareness of physicians. In our small series of 10 patients, all patients had prolonged (>1 -month duration) and moderate to severe limitations of shoulder ROM and were diagnosed as frozen shoulder; thus, full-blown frozen shoulder may also develop after COVID-19 vaccination. A description of frozen shoulder after COVID-19 vaccination is virtually absent from the orthopedic literature.²¹

Although there have been detailed descriptions of the cytokine and inflammatory cells mediated pathogenesis, a true scientific explanation behind the causation and etiology of idiopathic frozen shoulder is still unclear.¹¹ Scientific explanation of the causation that links the occurrence of frozen shoulder after heart or breast surgery is also not known. Thus, it may also be difficult for physicians to appreciate the development of frozen shoulder after vaccination because of an absence of a well-understood basic etiopathogenetic mechanism. But there have been earlier reports on shoulder stiffness and frozen shoulder after influenza vaccination.^{1,8} Furthermore, a recent increase in the presentation of frozen shoulder immediately after the vaccination, as seen in our series, should be an eye-opener and should lead to further research and improvement of our understanding behind the frozen shoulder etiopathogenesis. Could the frozen shoulder etiology be immune mediated? Localized autoimmune reaction has been investigated and stated as one of the etiological factors responsible for the development of idiopathic frozen shoulder in past reports.^{3,4} Vaccines are supposed to be absorbed locally and induce a local antibody response; However, any inadvertent systemic absorption of the vaccine and transfection to distant sites by the deltoid vasculature may lead to the rare autoimmune response against the transfected tissues.¹⁵ Autoimmune conditions such as Guillain-Barre syndrome and thrombosis with thrombocytopenia syndrome after vaccination have been theorized to occur as a result of similar systematic transfection of the vaccine and resultant autoimmune response to nerves and platelets.¹⁵ It may be possible that

Table I
Clinical features of 10 patients with frozen shoulder after COVID-19 vaccination.

Serial number	Age	Sex	Side affected	Dominant side	Vaccine	Comorbidity	Pre-existing mild intermittent shoulder pain?	Onset of symptoms from vaccination (days)	Duration of symptoms (weeks)
1	50	M	Left	Right	Covishield	Diabetes	Yes	Immediate	8
2	60	W	Left	Right	Covishield	None	Yes	Immediate	10
3	47	W	Left	Right	Covishield	Hypothyroid	Yes	Immediate	6
4	44	W	Left	Right	Covishield	Hypothyroid	No	2	8
5	57	W	Left	Right	Covishield	Diabetes	No	Immediate	6
6	43	W	Left	Right	Covishield	Prediabetic	No	Immediate	7
7	53	W	Right	Right	Covishield	Prediabetes	No	10	7
8	50	W	Left	Right	Covaxin	Hypothyroid	Yes	10	8
9	68	W	Left	Right	Covishield	Diabetes	No	Immediate	18
10	58	W	Right	Left	Covishield	None	No	10	6

M, man; W, woman.

Table II
Clinical features, follow-up, range of motion, and pain scores of 10 patients with frozen shoulder after COVID-19 vaccination.

Serial number	VAS pain score at presentation	Shoulder ROM at the time of presentation			Follow-up duration (months)	ROM resolution at follow-up	Pain resolution at follow-up
		Elevation (°)	ER (°)	IR			
1	5	90	25	SI	2.5	20%	70%
2	7	135	30	SI	1	20%	20%
3	8	110	45	SI	1.5	20%	90%
4	8	90	30	L4	1.5	0%	20%
5	8	68	27	SI	Lost		
6	8	135	35	L1	1.5	0%	0% (no recovery)
7	6	94	20	SI	2	0%	0% (no recovery)
8	8	80	40	SI	1	0%	0% (no recovery)
9	5	100	15	SI	0.5	0%	0% (no recovery)
10	2.5	130	20	GT	1	0%	50%

ER, external rotation; GT, greater tuberosity; IR, internal rotation; L1, first lumbar vertebrae; L4, fourth lumbar vertebrae; ROM, range of motion; SI, sacroiliac joint; VAS, visual analog scale. 0 = no pain; 10 = maximum pain possible.

vaccine transfection to local capsular tissue or nerves may have elicited an autoimmune response leading to the development of a frozen shoulder. The other possible reasons for SIRVA that have been described but largely unproven are that there may be an antigen-antibody reaction because of the injection of the antigen in the subacromial-subdeltoid bursa, thus leading to acute and prolonged hyperinflammatory reaction.⁵ Overpenetration, wrong site, and wrong vaccination technique have also been frequently implicated as possible mechanisms.^{1,13} A true explanation behind the causation may need a detailed scientific study and may be needed in the future, but a recognition of this possible etiology may at a minimum save the patient from a delay in diagnosis by an early recognition of the problem. There were 9 women and 1 man in our cohort with an average age of 53 years; our finding agrees with earlier reports that the average age is around 51 years,¹³ and women are more likely to be affected by SIRVA.¹ The onset of symptoms after vaccination was immediate in 6 patients, at 48 hours in 1 patient, and at 10 days in 3 patients. SIRVA has been defined as the development of shoulder symptoms within 48 hours of vaccination,¹³ but this definition is for medicolegal purposes and is not a true diagnostic criterion.¹ Earlier reports on SIRVA after influenza vaccine have included patients with compensation claims for the vaccination injury¹³; hence, those patients were incentivized not to reveal the true extent of symptom severity or resolution.¹³ In contrast, our series includes patients from an orthopedic surgeon's practice, and there were no compensation claims on the part of the patients.

In our series, adhesive capsulitis developed after the non-replicating viral vector vaccine (Covishield) in 9 cases (90%) and after the inactivated whole virus vaccine (Covaxin) in 1 case (10%). However, Covishield has been used in overwhelmingly higher numbers than the Covaxin in our country; therefore, it is difficult to

indicate a link between the type of vaccine administered and the shoulder symptoms. Covishield is a nonreplicating adenoviral vector vaccine (ChAdOx1 nCoV-19) produced by Serum Institute of India in collaboration with AstraZeneca. Covaxin is an inactivated viral vaccine (BBV152) developed by Bharat Biotech. The Pfizer/BioNTech vaccine (BNT162b2) and the Moderna vaccine (mRNA-1273) are both messenger RNA-based vaccines that contain messenger RNA molecules encapsulated inside lipid nanoparticles; these are the 2 most common vaccines used in North America.⁹ The presence of pre-existing mild shoulder pain before vaccination was also noted in the clinical history in 4 patients. It is unclear if the pre-existing mild intermittent pain represented any pathology because the patients did not seek treatment for the mild pain; mild intermittent pain is perceived as a normal occurrence by many patients. Hence, we recommend that if the patients have any pre-existing mild shoulder pain, vaccination should be taken with due caution, especially in terms of the technique, as their shoulder symptoms may worsen after the vaccination.

Eight of 10 patients had comorbidities that included diabetes, thyroid disorder, and prediabetes. Earlier reports have also noted that diabetes and thyroid disorders are risk factors for developing idiopathic frozen shoulder.²⁰ Hence, the possibility of frozen shoulder should be considered in a patient with comorbidity who develops painful stiffness after the vaccination.

Complete recovery of ROM and pain in frozen shoulder may take more than 1 year¹⁰; earlier reports on SIRVA after influenza vaccination have reported that recovery may continue for more than 6-12 months.¹ Thus, we expect our patients to have a protracted course of recovery that may last up to a year or even more.

Our study suffers from certain limitations. The present study is a retrospective study on a small number of patients. Currently, vaccination is the most effective strategy against COVID-19. Our

article is reporting only a rare problem after the vaccine, and it is not meant to raise doubts about the efficacy or overall usefulness of the vaccine.

Frozen shoulder after COVID vaccination has not yet been reported, and a longer follow-up is not yet available. A larger study and a longer follow-up will be needed and is currently underway to accurately define the prognosis and significance of the frozen shoulder after vaccination. However, by describing this hitherto unreported problem after COVID-19 vaccine, we hope that frozen shoulder after vaccination can be identified and treated appropriately and timely.

These side effects of COVID-19 vaccines, such as frozen shoulder, may likely be seen more commonly in the future because of the number of vaccine doses already crossing a figure of 900 million in India, 396 million in the United States, and 6 billion worldwide.¹²

Conclusion

Health care personnel who administer the COVID-19 vaccine needs to be educated about the importance of proper care, especially in subjects with pre-existing shoulder pain. Health care providers, especially orthopedic surgeons, who will see patients with significant shoulder pain and stiffness should be aware that frozen shoulder can occur after COVID-19 vaccination; hence, such patients should be identified and treated early. Patients after COVID-19 vaccination may develop frozen shoulders that will need to be treated for an extended period.

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