

## Shoulder Injury Related to Vaccine Administration After Covid-19 Vaccination: A One-Year Observational Single-Center Study

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### Keywords:

COVID-19 Vaccine; Shoulder Pain; Constant-Murley score; Shoulder steroid injection; Manipulative release

### Abbreviations:

DR: Digital Radiography; MR: Magnetic Resonance; NRS: Numeric Rating Scale (NRS); BMI: Body Mass Index

## 1. Abstract

Due to widespread vaccination caused by the global COVID-19 pandemic, a large proportion of the population has experienced shoulder pain after vaccination. Shoulder injury related to vaccine administration (SIRVA) may occur when the vaccine is not administered properly. The electronic medical data of patients with shoulder pain who visited the pain Department of the First Affiliated Hospital of Soochow University from April 1, 2021 to April 1, 2022 were queried. Vaccination details, Numerical Scoring Scale (NRS), and Constant-Murley score were collected at baseline and at 1, 3, and 6 months' post-treatment follow-up. There were 461 patients with shoulder pain, all were vaccinated. 6 of the 461 patients (1.3%) developed shoulder pain within 48 hours. 3 individuals underwent MRI, which indicated rotator cuff injury and inflammation. 4 of 6 patients (66.7%) has restriction of mobility, mean duration (weeks) was  $19.0 \pm 8.2$ , the rest was 12 and 16. The mean patient age was  $56.8 \pm 6.4$  years. No patient with previous/new COVID-19 infection during the study. 2 patients had mild comorbidity. None had elevated inflammatory markers. Manipulative

release of shoulder under brachial plexus block was performed in patients with limited mobility. All patients received shoulder steroid injection. All patients were satisfied with the therapeutic

effect. The features show that, incorrect vaccination injection can damage the shoulder joint and cause pain, it tends to occur in quin- quagenarian. Physicians should ask about vaccination history and assess the occurrence of SIRVA. Shoulder steroid injections and manipulation can be reserved for refractory cases.

## **2. Introduction**

Vaccination is effective in reducing severe illness, hospitalization and mortality caused by COVID-19 and is being rolled out in almost all countries [1]. Such widespread, all-age vaccination is unprecedented, and this is likely to cause many problems, and cases of vaccine-related pain continue to be reported [2-4]. Vaccine-related shoulder injury (SIRVA), which was previously reported for influenza and tetanus vaccines, was defined as shoulder pain and dysfunction that occurred within 48 hours after vaccination and persisted for more than 7 days [5]. SIRVA is associated with incorrect vaccination techniques, which can induce joint inflammation when vaccines are injected into the synovial tissue below the deltoid muscle. We observed cases of shoulder pain after vaccination, and magnetic resonance imaging (MRI) showed that the wrong way of vaccination may damage the shoulder structure and trigger inflammation. Billions of doses of vaccines have been administered globally to prevent COVID-19 during the pandemic, high-

lighting vaccine-related complications. Considering the reports after vaccination herpes, polymyalgia rheumatica (PMR) and related disease [6-8], the potential side effects associated with COVID-19 vaccination still need to be further explored. The public's consideration of vaccine-related complications and safety may cause vaccine resistance. The analysis of SIRVA can improve people's cognition of vaccines and then improve their attitude towards vaccination.

### 3. Material and Methods

This experiment was approved by the Ethics Committee of the First Affiliated Hospital of Soochow University (agreement number: 2022407). Written informed consent was obtained for the release of patient information and images. Vaccination details, numerical rating scales (NRS) and Constant-Murley scores were collected at baseline and 1, 3, 6 months after treatment by telephone and face-to-face interviews. Additional data on patients with SIRVA were retrospectively collected through the pain Department's electronic medical record system.

#### Participants

Eligibility criteria were patient ages > 18 years, a new onset of shoulder pain lasting more than 7 days, and a history of COVID-19 vaccination within 48 hours. The exclusion criteria were a history of other vaccination within 3 months, pain in the shoulder opposite the injection site, history of shoulder injury within 12 months, radiological examination revealed severe degenerative changes, fractures, tumors, and infections of the shoulder joint, unclear vaccination history.

#### Variables

Age, gender, latency, duration, Body Mass Index (BMI), vaccine manufacturer, comorbidity, active range of motion of shoulder joint, NRS score, Constant-Murley score, imaging and type of treatment were extracted through electronic medical records and telephone and face-to-face interviews.

#### Statistical Analysis

Descriptive statistics are used to calculate percentages of variables and standard deviations of continuous variables.

### 4. Results

#### Participant

There were 461 patients with shoulder pain, all of whom received the COVID 19 vaccine. 443 people who did not meet the inclusion criteria, 10 patients could not be contacted, 2 patients were unable to provide vaccine details. There were 6 of 461 patients (1.3%) developed shoulder pain within 48 hours after COVID-19 vaccine

injection (Figure 1). All 6 patients received conservative treatment before presentation, 4 people took NSAID orally and 2 were treated with external plaster. No patient with previous/new COVID-19 infection during the study. There were 2 patients had comorbidity. Patient 4 has Sjogren's syndrome for more than a decade, well controlled by taking hydroxychloroquine 0.2g QD and prednisone acetate 2.5mg QD. Her erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) remained normal after SIRVA. Patient 5 had a 17-year history of type 2 diabetes, by oral metformin and insulin injections, with moderate glycemic control and a transient increase after cortisol injections. The other patients had no autoimmune disease, diabetes, cancer, Parkinson's disease, or thyroid disease, examination during the course of the disease was normal (Table 1).

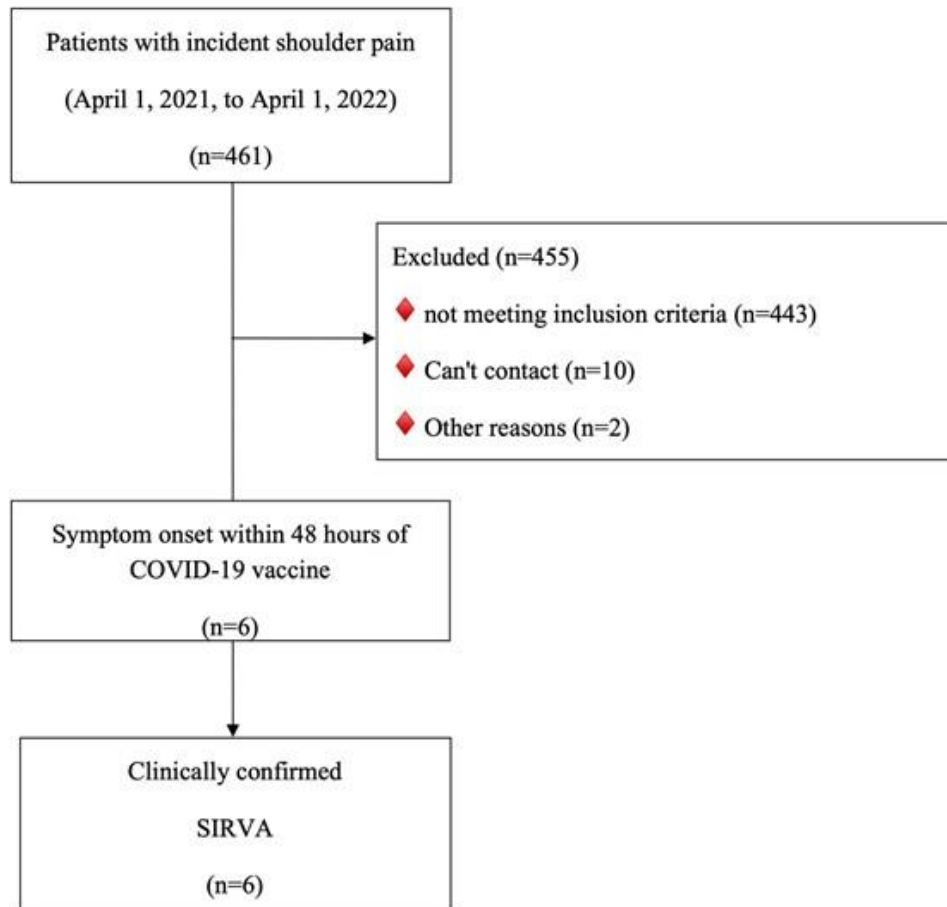
Patient 4 has a history of Sjogren's syndrome more than 10 years. Currently taking hydroxychloroquine 0.2g QD and prednisone acetate 2.5mg QD and well controlled. Her erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) remained normal after SIRVA. Patient 5 has a 17-year history of type 2 diabetes, which was controlled by oral metformin and insulin injections, with moderate glycemic control.

#### Descriptive Data

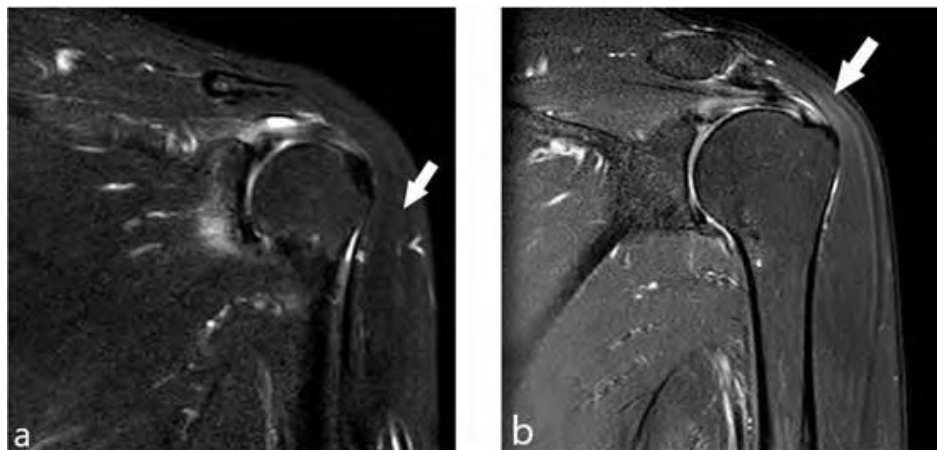
There were 6 people considered a diagnosis of SIRVA. 4/6 (66.7%) were women and 2/6 (33%) were men. The mean patient age was  $56.8 \pm 6.4$  years, BMI was  $22.7 \pm 3.8$  (18.7, 28.9). 1 patient shoulder pain occurred within 1 day, with the minimum BMI. SIRVA was present in three vaccines, Kconvac, Sinovac, and Sinopharm (Table 1). There were 4 of 6 patients has severe restriction of active and passive mobility of the shoulder joint. 3 individuals underwent MRI, which indicated rotator cuff injury and intraarticular inflammation, and 3 individuals underwent digital radiography (DR), which indicated mild degeneration (Figure 2).

#### Outcome Data

All patients received shoulder steroid injections, 4 patients with active and passive mobility of the shoulder joint were performed manual release under brachial plexus block, 2 patients were treated with internal heat injection, 1 patient performed pulsed radiofrequency of the subscapular and axillary nerves. The baseline mean NRS score was  $7.1 \pm 0.4$ , 1 month after treatment was  $0.8 \pm 0.4$ , 3 months after treatment was  $1.2 \pm 0.4$ , 6 months after treatment was  $0.8 \pm 1.2$ . The baseline mean Shoulder joint function score (Constant-Murley score) was  $49.2 \pm 5.4$ , 1 month after treatment was  $84.2 \pm 8.0$ , 3 months after treatment was  $78.7 \pm 8.9$ , 6 months after treatment was  $82.7 \pm 11.4$ . Within 6 months after treatment, all patients were satisfied with the therapeutic effect (Table 1).



**Figure 1:** Patient with shoulder pain in the pain department between April 2021 and April 2022. Abbreviations: Coronavirus disease 2019 (COVID-19), vaccine-related shoulder injury (SIRVA).



**Figure 2:** Imaging features of 2 patients confirmed SIRVA. (a) 12 weeks after patient 4 received the vaccine, arrows indicate soft tissue inflammation on the T2 adipose suppressor sequence in the coronary artery. Fluid accumulation in the deltoid bursa may be due to vaccine-induced inflammation. (b) MRI of patient 2 at 28 weeks after vaccination, arrow showing supraspinatus myopic hypersignal shadow and mild inflammation in shoulder joint.

**Table 1:** Cases of shoulder injury related to COVID-19 vaccination administration.

Patient	1	2	3	4	5	6
Gender	M	M	F	F	F	F
Age (years)	58	67	47	55	56	58
Dose	2	1	3	3	2	3
Vaccine type	KCONVAC	Sinovac-CoronaVac	Sinovac-CoronaVac	Beijing Institute of Biological Products	Beijing Institute of Biological Products	Beijing Institute of Biological Products
Onset after vaccination (days)	2	2	1	2	2	2
Duration (weeks)	24	28	12	12	16	12
BMI	22	25.7	18.7	20.8	28.9	20.3
Comorbidity	None	None	None	Sjogren's syndrome	Diabetes	None
Imagine	DR	MR	MR	MR	DR	DR
Diagnosis	Adhesive capsulitis	Adhesive capsulitis, Bursitis, Supraspinatus tear	Adhesive capsulitis, Bursitis, Supraspinatus tear	Adhesive capsulitis, Bursitis, Supraspinatus tear	Periarthritis of shoulder	Periarthritis of shoulder
Treatment	Manipulation once, Shoulder steroid injection once	Manipulation once, Shoulder steroid injection once, internal heated needle once	Manipulation once, Shoulder steroid injection thrice, internal heated needle once	Shoulder steroid injection once, nerve pulse radiation frequency twice	Shoulder steroid injection once	Shoulder steroid injection once
Pain degree (NRS)						
Baseline	7	7	7	8	7	7
6 months after treatment	0	3	1	0	1	0
Constant and Murley score						
Baseline	56	49	41	52	52	45
6 months after treatment	93	67	91	72	80	93

## 5. Discussion

### Inappropriate Injection May Lead to SIRVA

The main way of vaccination is injection, which can be divided into intradermal, subcutaneous and intramuscular injection. Choosing the right injection technique allows the vaccine to reach the desired site and produce a good immune response. Pain during vaccination is one of the sources of iatrogenic pain, local pain after vaccination is common and is usually mild and self-limited [9]. Improper needles and injection methods may exacerbate pain and cause injury. So far, the recommended method of COVID-19 vaccination is intramuscular, may cause a more serious complication of vaccine-related shoulder pain, defined as shoulder pain that develops within 48 hours of vaccination and lasts for more

than 7 days, possibly with limited mobility. SIRVA is associated with mechanical and chemical damage to the shoulder joint caused by improper injection techniques [5]. Thinner people have thinner subcutaneous tissue and seem to be more prone to needle penetration, fat people are also prone to erroneous injections due to poor positioning. But in this study, SIRVA occurred in 6 of 461 (1.3%) patients within 1 year, 4 of 6 (66.7%) had a normal BMI. It is suggested that the incidence of SIRVA is not high, but it is also easy to occur in normal size people. MRI examination was performed in 3 patients, all of which showed deltoid bursa effusion and supraspinatus tendon injury. Due to the upward or upward angle of the puncture point, too deep injection may directly cause injury to the supraspinatus tendon, and subsequent injection of liquid may further aggravate the injury. A vaccine mistakenly injected into the

deltoid slide capsule can spread into the joint, causing a strong immune response that can last for months, causing pain and limited movement [10-14]. Due to the lack of MRI before vaccination/within 1 week after vaccination, the supraspinatus tendon injury cannot be determined whether it is caused by needle tip injury. In this study, MRI was performed at 12 and 28 weeks after SIRVA, which indicated that all 3 patients had different degrees of intra-articular effusion and rotator cuff injury.

### **SIRVA prone population**

Risk factors for SIRVA are female, lean, and thin deltoid muscles [15], the current report indicates it tends to occur in quinquagenarian [2], the average age of the study was  $56.8 \pm 6.4$  years. It is suggested that the vaccine incorrectly injected into the deltoid bursa may act as an antigen and trigger an inflammatory response, this inflammatory reaction is easy to get out of control in the susceptible age of scapulohumeral periarthritis. The longest duration of the disease in this study was 28 weeks, and his magnetic resonance imaging still suggested significant fluid accumulation and tissue inflammation in the joint. Reports indicate that people with comorbidities seem to be more vulnerable to the vaccine [16], in this study 4 people had no comorbidities, 1 had diabetes and 1 had Sjogren's syndrome. There was no increase in inflammatory markers and no change in comorbidities in any of the patients. This may indicate that inflammation in the shoulder does not trigger a systemic immune response. The data from this study suggest that SIRVA can occur in healthy people, it is suggested that all patients with new onset shoulder pain should be noted, vaccination details need be collected to identified SIRVA.

### **Shoulder Steroid Injections and Manipulation Can Be Reserved for Refractory Cases**

Shoulder steroid injections can improve pain and range of motion in patients with adhesive capsulitis of shoulder by suppressing immune responses [17], but whether it could weaken an individual's immunity and thus increase susceptibility needs to be fully considered. Articles have pointed out that the impact of shoulder steroid injections on people's immunity during the COVID-19 pandemic is unclear, with no evidence that it increases the risk of contracting the virus or alters the clinical course of disease in asymptomatic virus carriers [18]. Whether corticosteroid injections for pain affect the efficacy of COVID-19 vaccines? Vaccination is an active immune process that induces a powerful immune response and establishes an effective immune memory through B-cell and T-cell dependent mechanisms [19]. All immune cells express glucocorticoid receptors, so all steps of the immune response are affected by exogenous glucocorticoids [20]. But there is currently no direct evidence that corticosteroid injections before or after the COVID-19 vaccine reduce its effectiveness. The study recommends that doctors should consider timing corticosteroid injections, if possible at least two weeks before and at least one week after the COV-

ID-19 vaccine. This conclusion was based on the time window of suppression of the hypothalamic-pituitary-adrenal (HPA) axis after intraarticular corticosteroid injection and the time window of peak efficacy of COVID-19 vaccine [21]. All patients in this study received shoulder steroid injections, 4 people received one injection and 1 person received three injections. The patient with mobility restriction of shoulder joint were released by manipulation under brachial plexus block. This study showed that within 6 months, the patients with SIRVA experienced relief of pain and good recovery of shoulder function after the above treatment. SIRVA may be a self-limiting disease and there is no standard treatment. Treatments reported so far include clinical observation, oral non-steroidal anti-inflammatory drugs, oral steroidal hormones, physical therapy and even surgical treatment [10, 13, 22]. The average disease duration in this study was  $19.0 \pm 8.2$  weeks, the shortest was 12 weeks and the longest was 28 weeks. It is suggested that some patients could not recover or even deteriorate in a period of time through clinical observation or conservative treatment with oral drugs. For refractory cases, shoulder steroid injection may obtain better therapeutic effect. If there is a combination of adhesive shoulder bursitis, it is necessary to perform a manipulative release of the shoulder under brachial plexus block.

### **6. Limitations**

This is a single-center retrospective study, there was recall bias during follow-up. There was no film at the time of vaccination, the correctness of the procedure could not be judged by recall, and no patient underwent MRI immediately after SIRVA. In this study, only patients who came to the hospital were recorded, and these cases were likely to be refractory. There's a subset of cases that can cure themselves without going to the hospital, and those people are being missed.

### **7. Conclusion**

Health care providers should be aware that incorrect vaccination can damage the shoulder joint and cause pain, it tends to occur in quinquagenarian, delayed treatment may worsen the condition. SIRVA can occur from different vaccine manufacturers. The doctor should ask about vaccination history and assess the occurrence of SIRVA. Shoulder steroid injections and manipulation can be reserved for refractory cases.

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#### **Conflicts of Interest**

The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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