

Literature Review

Shoulder Injury Related to Vaccine Administration Following COVID-19 Vaccination

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Abstract

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Shoulder Injury Related to Vaccine Administration (SIRVA) is a general term that describes a complaint of shoulder pain and limited range of movement within 48 hours after vaccination. With mass vaccination due to the COVID-19 pandemic, the incidence of SIRVA is expected to increase. Symptoms include pain, stiff shoulders, limited movement, and weakness. The pathophysiology of SIRVA is not fully understood, but it is believed to occur due to an excessive immune response due to inappropriate injections. Earlier studies on SIRVA have highlighted a significant gender gap, indicating a higher prevalence among females. To date, there is no established standard method for assessing SIRVA, but magnetic resonance imaging (MRI) is the imaging of choice for detecting SIRVA-related abnormalities, such as hematoma, infection, intraosseous edema, subacromial bursitis, joint synovitis, adhesive capsulitis, tendonitis, and rotator cuff injuries. The first line pharmacological therapy that can be given is nonsteroidal anti-inflammatory drugs (NSAIDs). If there is no improvement, an intra-articular corticosteroid injection can be given. It can also be supported by physiotherapy to increase muscle strength in the area of the injured part. SIRVA can be prevented by understanding the anatomy of the shoulder and the appropriate injection technique.

Introduction

Shoulder Injury Related to Vaccine Administration (SIRVA) is a general term that describes a complaint of shoulder pain especially in the deltoid muscle, where the vaccine is injected intramuscularly.¹ The National Vaccine Injury Compensation Program stated that SIRVA is defined as pain in the shoulder accompanied by a limited range of movement within a minimum of 48 hours after vaccination, where there is no previous history of pain or inflammation in the shoulder. If left untreated it can lead to permanent disability.² The most common cause of SIRVA is a method of administering the vaccine that does not comply with protocol, which could be in the form of an injection site that is too high or deep, thereby triggering an inflammatory or immune response at the injection site and injuring the surrounding muscles or blood vessels.³ SIRVA is not

only caused by certain vaccines but varies. Atanasoff et al reported the largest contributor to SIRVA was the influenza vaccine (62%), followed by the Tetanus vaccine (15%), Tetanus, Diphtheria, Pertussis vaccine (15%), and Human Papillomavirus (HPV) vaccine (8%).² In addition, due to Corona Virus Disease 2019 (COVID-19) pandemic in 2020, there was an increase in reports of SIRVA. The first case of SIRVA after COVID-19 vaccination was reported by Tatiane et al. in April 2021, where the patient reportedly suffered from subdeltoid bursitis and rotator cuff tendinopathy after vaccination.⁴

The coronavirus disease 2019 (COVID-19) pandemic is a worldwide occurrence of a viral outbreak caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was first identified in China in December 2019 and quickly spread worldwide.⁵ Several efforts have been made to provide

acquired immunity against COVID-19, including implementing a mandatory vaccination policy.⁶ Although it has been proven to reduce COVID-19 incidence, hospitalization, and mortality rate, such mass vaccination can increase the incidence of SIRVA.^{7,8} The estimated incidence of SIRVA according to a previous study performed by Hibbs et al. in 2020 is 1.5-2.5% and it is estimated to increase after mass COVID-19 vaccination. However, SIRVA is often underestimated so reported incidents are inaccurate.⁹ SIRVA can be an extremely painful condition and can decrease patients' range of motion which can last for weeks to months or as long as years.³ It can interfere with daily activities, reduce patients' quality of life, and result in long-term impacts on biological, psychological, and social well-being. Therefore, this literature review aimed to describe the SIRVA following COVID-19 vaccination.¹⁰

Results

Definition

Shoulder Injury Related to Vaccine Administration (SIRVA) is a term to describe complaints of shoulder pain that occur due to vaccination injection techniques that do not comply with the protocol. This term was first introduced in 2010 by the Vaccine Injury Compensation Program (VICP) and was officially added to the Vaccine Injury Table in 2017. SIRVA can actually be prevented if medical personnel can understand the correct vaccine injection technique and recognize the anatomy of the shoulder itself. In certain conditions, the place where the vaccine is injected is too high into the glenohumeral joint so that it is not placed in the deltoid muscle but rather in the shoulder capsule. If the injection location is too low or to the side, it can cause damage to the axillary and radial nerves and lead to less common symptoms such as neuropathic pain and paralysis. Symptoms that arise in SIRVA include stiff shoulders, pain, limited movement, and weakness.⁹

Several pharmacovigilance institutions discuss the criteria for SIRVA. Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) states that SIRVA occurs at onset 24-48 hours after vaccination, and there is suspicion of an error in the vaccine injection technique, causing a group of clinical manifestations such as pain when moving the shoulder, limitations in ROM, and the presence of abnormalities on imaging such as connective tissue and joint capsule injury which includes deltoid muscle bursitis, tendonitis, rotator cuff tear, or adhesive capsulitis.¹¹ In addition, the Vaccine Adverse Event Reporting Scheme (VAERS) and the Vaccine Injury Compensation Program (VICP) define SIRVA as complaints of pain in the shoulder within 48 days after vaccination, accompanied by limitations in ROM, provided there is

no nerve damage or history of pain and inflammation.¹² However, it turns out that there are several articles that discuss the criteria for SIRVA which include the presence of nerve damage.¹³ This is in accordance with the previous explanation that the wrong vaccination injection location can injure the axillary and radial nerves and lead to other complications such as bursitis, radial nerve injury, and axillary nerve injury.

When it comes to patients with underlying chronic shoulder pathologies, it can be difficult to determine if an acute exacerbation of pain after vaccination is caused by SIRVA, or if it is simply a natural progression of the existing condition. Patients with chronic shoulder pathologies often experience pain and limited range of motion, which complicates the diagnosis of SIRVA. However, patients with pre-existing shoulder injuries or conditions may be at a higher risk of developing SIRVA due to the increased sensitivity or vulnerability of the shoulder joint. The injection of the vaccine into an already compromised shoulder can exacerbate symptoms and lead to a more pronounced inflammatory response. Currently, there is limited literature discussing SIRVA in patients with chronic shoulder injury, but a prospective study conducted by Servet Iğrek et al. found that patients with pre-existing chronic pathologies experienced a significant increase in Visual Analog Scale (VAS) scores before and after vaccination. In contrast, patients without any shoulder injury or condition did not experience a significant difference in VAS scores.¹⁴

Epidemiology

SIRVA is reported to increase every year, the following is the prevalence of SIRVA caused by certain types of vaccines.

Pathophysiology

The pathophysiology of SIRVA is not fully understood, but it is believed to occur due to an excessively strong immune response to the vaccine antigen.^{16,17} A study on SIRVA following influenza vaccination conducted by Hirsiger et al. has indicated that vaccine application in an inappropriate tissue compartment is associated with chronic immune activation. In that study, it was observed that patients with vaccine-associated tissue damage, especially those with bone erosions, displayed a significantly higher occurrence of CD19+CD27+CD38+ plasmablasts and CD4+CD45RO+CXCR5+ Tfh-like T cells in their peripheral blood. The frequencies of plasmablasts (PB) and Tfh-like T cells were correlated and fell within the range typically observed only transiently 1-2 weeks after influenza vaccination. These findings suggest a potential pathological immune dysregulation in cases of SIRVA. The persistence of plasmablasts and Tfh-like T cells in the peripheral blood of SIRVA cases several months after vaccination may indicate ongoing

Table 1. Epidemiology of SIRVA

Author	Year	Sample	Prevalence
Hesse EM, et al. ¹⁵	2010 - 2016	489	<ul style="list-style-type: none"> • Inactivated influenza = 400 (84.0%) • Tetanus, diphtheria, pertussis = 57 (12.0%) • Pneumococcal conjugate = 11 (2.3%) • Tetanus, diphtheria = 6 (1.3%) • Pneumococcal polysaccharide 4 (0.8%) • Hepatitis A = 3 (0.6%) • Hepatitis B = 2 (0.4%) • Meningococcal conjugate = 2 (0.4%) • Measles, mumps, rubella = 1 (0.2%) • Human papillomavirus = 1 (0.2%) • Other / unspecified = 2 (0.4%)
Mackenzie LJ et al. ⁹	2017 - 2021	505	<ul style="list-style-type: none"> • Unknown = 208 • COVID-19 AstraZeneca = 95 • Influenza = 68 • COVID-19 Pfizer = 52 • COVID-19 Moderna = 31 • Pneumococcal = 17 • DTaP, Tdap, DTaP + polio = 12 • COVID-19 unknown = 11 • Herpes zoster = 6 • MMR = 3 • HPV = 3 • Hep A = 2 • COVID-19 Janssen = 1 • HIB + meningococcal = 1 • Polio = 1 • Varicella = 1 • Meningococcal = 1

immune activation. In fact, SIRVA was associated with an activated T cell phenotype characterized by CD69+ and CD154+ expression, particularly in Tfh-like T cells, and this activation was correlated with the frequency of plasmablasts.¹⁸

Furthermore, improper intramuscular injection into anatomic structures near the deltoid muscle may result in chemical and/or mechanical trauma. Injection into less vascularized subcutaneous tissue or adjacent bursae, tendons, and nerves can potentially lead to the development of SIRVA because it can reduce immunogenicity, therefore reducing the effectiveness of the vaccine and causing pain.^{17,19} The injection that is placed too deep into the shoulder capsule can result in inflammation of the shoulder joint or its surrounding bursa (synovitis), or it may lead to an infection like septic arthritis or bursitis. An injection placed into the rotator cuff area can cause injuries to the rotator cuff, such as tendonitis or a tear. Placing an injection into the subacromial or subdeltoid space can cause painful inflammation (bursitis) and potentially lead to a condition known as frozen shoulder (adhesive capsulitis). If the injection is administered into or near the axillary nerve, it may cause nerve irritation, resulting in numbness and tingling (paresthesia), and in some cases, it may cause temporary weakness in the arm due to anterior or middle deltoid paralysis.^{1,3}

Risk Factors

The risk factors for SIRVA include female gender, thin habitus, having small deltoid muscle bulk, and improper injection techniques.^{9,20} Earlier studies on SIRVA have highlighted a significant gender gap, indicating a higher prevalence among females, with some research reporting rates as high as 82.5% of cases being female.^{12,15,21} The higher incidence of SIRVA in females is caused by several factors including a low body mass index, reduced thickness of the deltoid fat pad and/or muscle bulk, higher vaccination participation among females, increased rates of reported adverse events, or greater tendency for females to seek medical care. Modesty could potentially be another contributing factor, as females might be more inclined to roll up their sleeves or pull down their shirts to expose the deltoid, as opposed to males who might be more likely to remove their shirts entirely. However, it's important to note that there is currently no primary research available in this specific area. Further research is necessary to better understand the reasons behind these gender disparities in SIRVA cases.⁽⁹⁾ In a recent report conducted by Atanasoff et al., the patient was also an elderly female with a thin body habitus. The authors suggest that inadequate technique, combined with smaller body habitus, may increase the risk of unintentional injection into the subacromial bursa or underlying bone.²²

Clinical Evaluation

For patients experiencing persistent or worsening shoulder pain for more than 48 hours after vaccination, further clinical evaluation is necessary. The initial assessment should include gathering medical history to understand the correlation between the symptoms and the injection, as well as to rule out potential comorbidities or preexisting shoulder pathology.¹ The symptomatic hallmark of SIRVA is shoulder pain emerging within 1 to 2 days of vaccination in a shoulder that was previously asymptomatic and limitations in range of motion. In contrast to the typical post-vaccination shoulder pain, SIRVA-related pain persists beyond 1 week and does not resolve within that time frame.²³ In research conducted by Atanasoff et al., every patient reported experiencing shoulder pain. The initiation of pain was noted in 93% of cases within less than 24 hours after vaccination, and 54% reported pain immediately following the injection.²² Hesse et al. found that 31.1% of patients report limited shoulder ROM after injection.¹⁵ Due to pain and restricted movement, patients may encounter challenges in carrying out their daily activities.²³

After obtaining a medical history, a physical examination, especially in the shoulder area, is done. The physical examination of the shoulder begins with an inspection of the injection site, palpation, assessment of range of motion (ROM), muscle strength tests, and neurovascular examination.²⁴ It is recommended to expose both shoulders entirely, without clothing, to enhance visibility and facilitate the assessment of any asymmetry, skin changes, or swelling. Subsequently, gentle palpation of the site is conducted to detect any potential hematoma, fluctuance, abscess, or crepitus. Evaluation of shoulder range of motion should encompass both active (unassisted) and passive (assisted by the examiner) movements. The typical range of motion of the shoulder includes forward flexion of 150° to 180°, extension of 40° to 60°, abduction of 150° to 180°, internal rotation to the thoracic spine, and external rotation of 60° to 90°.¹ Additionally, ROM on the affected side should be compared with that of the unaffected side. Following that, strength testing can be conducted, focusing on assessing the integrity of the deltoid function. This involves testing the arm against resisted abduction (middle deltoid) and forward flexion (anterior deltoid). Nevertheless, distinguishing reduced strength from pain can be challenging and may necessitate additional evaluation through imaging.²⁴ Lastly, it is essential to conduct a comprehensive neurovascular examination. Vascular injuries are not acknowledged as a complication of SIRVA, and they can be promptly ruled out by palpating the brachial artery at the mid-arm medially or the radial artery at the volar-radial wrist.¹

Diagnostic Studies

To date, there is no established standard method for assessing SIRVA. Although X-rays are widely accessible, they are unlikely to produce positive or diagnostic outcomes in the early stages of the clinical course. Plain radiographs may be beneficial for examining arthritic changes in the glenohumeral joint to eliminate other potential causes of shoulder pain.⁽¹⁾ Nevertheless, findings from other studies suggest that X-rays are not effective in evaluating SIRVA. If available, magnetic resonance imaging (MRI) is the imaging of choice for detecting SIRVA-related abnormalities. It allows for the assessment of hematoma, infection, intraosseous edema, subacromial bursitis, joint synovitis, adhesive capsulitis, tendonitis, and rotator cuff injuries.²⁵ On MRI, the predominant observation is a fluid signal in the deep muscular or tendinous structures, often linked to inflammatory changes in the subacromial-subdeltoid bursa and focal bone marrow edema of the humeral head.²⁶ The use of contrast-enhanced MRI is recommended when an infection is suspected, as it provides clearer insights into osseous and non-osseous involvement and confirms the presence of tissue necrosis.¹ Currently, there is no specific guideline for the optimal timing of MRI; however, 63% of MRIs are typically conducted within three months of symptom onset.²⁷ In cases where an MRI is unavailable, ultrasound evaluation can be considered, offering clinical data for diagnoses related to SIRVA. Ultrasound can assist in identifying bursa abnormalities in individuals with bursitis.⁽¹⁾ Given that SIRVA is not a neurological injury, normal results are expected in nerve conduction, electromyographic studies, and neurological evaluations.²⁷ Nevertheless, for optimal results, it is recommended to do these evaluations at least 2-3 weeks after vaccination. This time frame facilitates the initiation of any potential nerve injury's sequence of changes in myelin sheath and axonal sheath, allowing the study to accurately identify such alterations.¹

Treatment

SIRVA is capable of causing a series of effects if the vaccination injection is misplaced. One condition that commonly occurs in SIRVA is subacromial-subdeltoid bursitis, which is the result of inflammation of the shoulder joint or its surrounding bursa (synovitis), or it may lead to an infection like septic arthritis or bursitis.²⁸ Thus, the first line of pharmacological therapy that can be given to SIRVA patients is nonsteroidal anti-inflammatory drugs (NSAIDs). If there is no improvement, an intra-articular corticosteroid injection can be given. Administration of NSAIDs or corticosteroid injections can be supported by physiotherapy to increase muscle strength in the area of the injured part. This is important because in certain conditions where there is immobilization of the

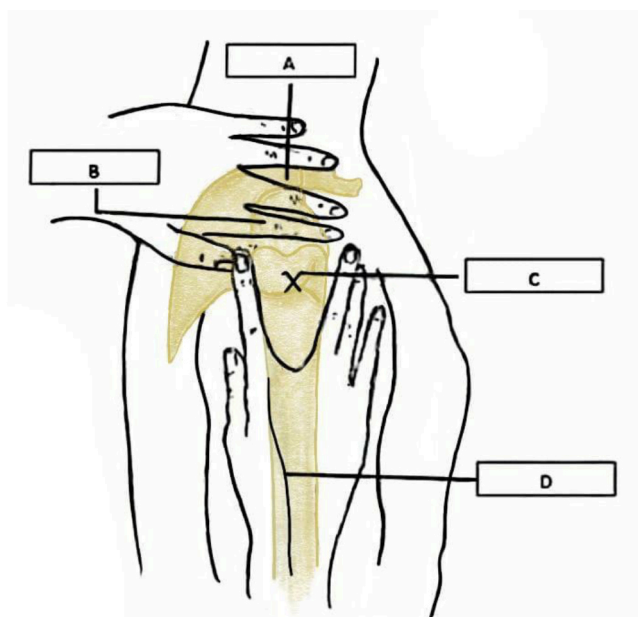


Figure 1. Injection Technique to the Deltoid Muscle a. Acromion, b. Bursa, c. Axillary nerve, d. Radial nerve

shoulder, it can lead to muscle atrophy and a frozen shoulder, which involves stiffness and pain in the shoulder joint.² In the case report conducted by Mackenzie LJ et al, the physiotherapy exercises carried out, including practicing flexion, external rotation, and abduction movements, were proven to reduce the pain scale and improve the range of movement.²⁹ several other pharmacological drugs can be given, such as topical diclofenac ointment and serratiopeptidase tablets. Sukhija S, et al. reported that the application of diclofenac ointment 3–4 times a day for 8–10 days was proven to reduce the local tenderness. In addition, if there is damage to the joint, surgery can be carried out in the form of reconstruction.²⁸ Arthrographic distension was also performed and showed significant results in the form of pain relief and increased range of movement. Recovery can take several weeks to several months, depending on each individual and how the therapy is carried out.³⁰

Prevention

SIRVA is a condition that can be prevented if the vaccine is administered according to a predetermined protocol. This can be supported by the ability to understand the anatomy of the shoulder which includes the deltoid muscle, axillary and radial nerves, bursa, and acromion. Not only that, it is also necessary to understand the appropriate injection technique so that it is not too deep or too shallow on the skin.³ Several things that medical personnel need to pay attention to when injecting vaccines:

- Determine the injection zone in the deltoid muscle by determining the upper and lower limits of a safe injection site. The upper limit is determined by

placing 2-3 fingers from the acromion. Two fingers are used for medical personnel who have larger fingers, while three fingers are used for those who have slimmer or smaller fingers. Meanwhile, the lower limit of this safe zone is the axilla. When you want to inject, the thumb and forefinger form a V-shape to keep the injection zone visible (Figure 1).³

- The appropriate shooting angle on the deltoid muscle is an angle of 90°.³
- The specific needle length is selected based on the patient's body shape and weight. A needle that is too long can penetrate the deltoid muscle and reach the bone. This can cause the vaccine not to be completely absorbed. On the other hand, if the needle is too short, the vaccine will be administered subcutaneously, resulting in the possibility of developing nodules or cellulitis.³

The following are CDC recommendations regarding appropriate needle sizes for vaccination. In addition, clinical judgment should be used when selecting needles.³¹

Table 2. Needle Length for Intramuscular Injections in Deltoid Muscle by Age

Age	Needle Gauge	Needle Length (mm)	Colors
Toddlers, 1-2 years	22-25	16-25	Blue, Purple, Orange
Children, 3-10 years	22-25	16-25	Blue, Purple, Orange
Children, 11-18 years	22-25	16-25	Blue, Purple, Orange
Adults, 19 years and older			
– 60 kg (130 lbs) or less		25	Blue
– 60-70 kg (130-152 lbs)		25	Blue
– Men 70-118 kg (152-260 lbs)		25-38	Blue, Black
– Women 70-90 kg (152-200 lbs)		25-38	Blue, Black
– Men 118 kg (260 lbs) or more		38	Black
– Women 90 kg (200 lbs) or more		38	Black

In patients with a history of chronic shoulder pathologies, it is essential to take extra precautions to minimize the risk of exacerbating the existing condition or causing SIRVA. In such cases, contraindications for administering injections in the shoulder area should be carefully considered. Exploring alternative sites like the ventrogluteal area for intramuscular injections may be beneficial, aiming to decrease potential discomfort and mitigate the risk of aggravating symptoms related to the shoulder. The ventrogluteal region is preferred due to its substantial muscle mass. It is considered both safer and less painful, given its distance from the superior and inferior gluteal arteries, as well as the sciatic and superior gluteal nerves.³² This site is also suitable for all ages including infants since the muscle

in the ventrogluteal site is sufficiently developed, even in infants aged 1 to 12 months. Particularly, in children aged 12 to 36 months, the ventrogluteal site exhibits greater thickness compared to the anterolateral site.³³

Conclusion

Shoulder Injury Related to Vaccine Administration (SIRVA) is a general term used to describe the occurrence of shoulder pain and restricted range of motion within 48 hours following vaccination. With mass vaccination due to the COVID-19 pandemic, its incidence is expected to rise. As of now, there is no universally accepted standard for assessing SIRVA, but MRI is the preferred imaging modality for identifying abnormalities. NSAIDs serve as the initial pharmacological therapy, and if no improvement is seen, intra-articular corticosteroid injections may be administered. Additionally, physiotherapy is recommended to enhance muscle strength in the affected area. Preventing SIRVA involves a comprehensive understanding of shoulder anatomy and the application of correct injection techniques.

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