Review Article

Shoulder Injury Related to Vaccine Administration

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ABSTRACT

Shoulder injury related to vaccine administration (SIRVA) is a rare yet increasingly recognized complication of immunization. Although a medicolegal term rather than a true diagnosis, SIRVA was introduced in 2010 by the Vaccine Injury Compensation Program after an increase in claims filed for vaccine-related shoulder injury. Patients typically present with severe pain and limited range of motion within 48 hours of vaccination and may experience notable functional limitations. Although the underlying pathophysiology is incompletely understood, the existing literature suggests that SIRVA results from the inflammatory response produced when the vaccine is injected into tissues containing a preexisting antibody. Current treatment modalities include physical therapy, corticosteroid injections, and antiinflammatory medications. In some cases, surgery may be required to treat underlying pathology, such as rotator cuff or biceps tendinopathy. Although the available literature indicates modest improvement in patients with SIRVA undergoing treatment, current data are limited to case series. Larger, high-quality studies are needed to determine the natural history and optimal treatment of this increasingly prevalent condition.

Shoulder injury related to vaccine administration (SIRVA) is defined by the National Vaccine Injury Compensation Program (VICP) as "shoulder pain with limited range of motion within 48 hours after vaccine receipt in individuals with no prior history of pain, inflammation, or dysfunction of the affected shoulder before vaccine administration."[1] Although shoulder pain is a common report after intramuscular administration of vaccine into the deltoid, injection site soreness is typically mild and transient, and has no effect on shoulder mobility.[2] However, a subset of patients may experience prolonged functional deficits due to severe pain and limited motion. The term SIRVA was first introduced in 2010 by a team of VICP physicians who reported on 13 petitioners presenting with severe vaccine-related shoulder pain persisting for more than 6 months.[3]

The VICP was established in 1988 to stabilize vaccine costs, ensure vaccine supply, and create a forum to adjudicate petitioner claims of vaccine-related injury. Initially authorized by the National Childhood Vaccine Injury Act of 1986, the VICP was originally intended for the evaluation of vaccine-related

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injuries in children. However, over time, the program demographic has shifted, with over 50% of claims now involving adults.[3] After the introduction of the term SIRVA by VICP physicians in 2010, alleged SIRVA petitions to the VICP increased substantially, particularly in relation to the influenza vaccine. Based on such petitions and the 2010 case series of Atanasoff et al, a 2012 Institute of Medicine report concluded that deltoid bursitis may be causally associated with immunization. As a result, in 2015, the VICP proposed the addition of SIRVA as a complication of immunization to the Vaccine Injury Table. This addition was confirmed on March 21, 2017[3] (Figure 1).

Although SIRVA remains a medicolegal term rather than a true diagnosis,[4] the incidence of this condition seems to be increasing. Ten claims were brought before the VICP in the fiscal year (FY) 2011; this number rose to 433 in FY2016[5] (Figure 2). SIRVA claims as a percentage of total petitioner claims have also increased from 1.8% in FY2011 to 40.7% in FY2016.[6]

In a review of the Vaccine Adverse Event Reporting System (VAERS) over a 7-year period, Hibbs et al[4] found the incidence of atypical shoulder pain and dysfunction after inactivated influenza vaccination (IIV) to range from 1.5% to 2.5%, with an average incidence of 2.0% overall. In contrast to the findings reported by the VICP, the authors noted a constant annual rate of injury over the study period. Given this discrepancy, the authors hypothesize that increased public awareness of SIRVA as a compensable injury, rather than a true increase in pathology, has contributed to a surge in claims over the past decade.[4] In limiting their review to cases of shoulder injury after IIV injection, the authors focused on a well-established vaccine with consistent rates of immunization. However, they are unable to comment on the incidence of SIRVA after other common immunizations, including the human papillomavirus and recombinant zoster vaccines, as well as on potential cases because of future vaccines.

With the recent development of the severe acute respiratory syndrome coronavirus 2 vaccine, healthcare providers anticipate a sharp increase in reported cases of SIRVA in the upcoming year.[7] Despite this, data surrounding this condition are limited to small case series and remain virtually absent from the orthopaedic literature. The purpose of this review was to summarize current understanding regarding the pathophysiology, presentation, and management of SIRVA and thereby raise awareness of this increasingly prevalent condition in orthopaedic practice.

Pathophysiology

The pathogenesis of SIRVA is incompletely understood. The most widely held theory posits that SIRVA occurs when vaccine is injected through the deltoid into underlying nonmuscular tissues, producing a prolonged inflammatory response.[1,3,6] In an early case series, Bodor and Montalvo used ultrasonography to localize the subdeltoid bursa in 2 affected patients and 21 healthy control subjects and found the bursa in all patients to be at a depth easily reached by the 1-inch needle used in cases of immunization. They hypothesized that because the subdeltoid bursa is contiguous with the subacromial bursa, injection of the vaccine material into the subdeltoid region could lead to bursitis, tendinitis, and capsulitis[8] (Figure 3). Atanasoff et al investigated this hypothesis in a later case series: In one patient, the path of vaccine administration was replicated intraoperatively by inserting a needle into the deltoid at a location preoperatively identified by the patient. The needle was found to pass through an area of inflamed bursa and scarred tendon before contacting a region of friable bone, leading the authors to infer a causal relationship between vaccine administration and the onset of pain.[3] However, because this investigation was conducted in only 1 of 13 patients, the authors were unable to comment on the reproducibility of their findings.

Other authors have expanded on this proposed mechanism of injury, noting that if the vaccine is inadvertently injected into the subacromial space of the shoulder, preexisting antibodies within the surrounding tissue may produce a prolonged inflammatory response that causes the symptoms typical of SIRVA.[9,10] In an animal study, Dumonde and Glynn[11] demonstrated that an antigen injected into the synovial space bound to the existing antibody within the periarticular connective tissue, leading to the formation of antigen-antibody complexes and acute inflammation lasting for 6 weeks. Although these findings have not been replicated in humans, Atanasoff et al[3] proposed that because of the perennial nature of immunization, SIRVA results from the injection of the vaccine antigen to which a patient has been previously sensitized after naturally occurring infection or earlier vaccination. However, because current research on the pathophysiology of SIRVA is limited to observational studies, it is not possible to definitely prove a relationship between immunization and the onset of SIRVA symptoms. Larger, high-quality studies are needed to further elucidate the pathogenesis of shoulder injury after vaccination.

Risk Factors

Case series implicate both patient-specific factors and vaccine-specific factors in the development of SIRVA. Early ultrasonographic studies of needle length in relation to anatomical structures suggested a greater risk of shoulder injury in patients with lower body mass index (BMI), because of the theoretical risk of overpenetration of the deltoid and subsequent injection of the subdeltoid bursa.[8,12] However, later case series disprove this, reporting BMIs ranging from normal to obese. Atanasoff et al[3] noted a mean BMI of 27.2, with 62% of patients overweight or obese, whereas Hesse et al[6] reported a median BMI of 25.1. Although it is conceivable that needle length or conversely soft-tissue mass about the shoulder could affect the depth of penetration during vaccination,[8,12,13] the development of shoulder injury after immunization seems to be related more to the injection technique than BMI.[3,6]

In contrast to BMI, sex and age do seem to play a role in the development of vaccine-related shoulder symptoms. In the two largest series of SIRVA cases to date, Hibbs et al and Hesse et al reported a predominance of female patients at 82.6%[4] and 82.8%,[6] respectively. These findings are consistent with an earlier case series, in which 85% of patients with SIRVA were women.[3] In addition to female sex, older age seems to be a risk factor for shoulder injury after vaccination. Hesse et al[6] reported a median age of 51 years in their review of 476 cases, with only one patient below the age of 18 years. Similarly, Atanasoff et al[3] found a mean age of 50 (range 26 to 83) years in their series of 13 patients. Despite the fact that children and adolescents undergo frequent vaccination, with children over the age of 3 years recommended to receive immunization in the deltoid, children are less likely than adults to file compensation claims for SIRVA. This may be due, in part, to the lower incidence of soft-tissue shoulder pathology in the pediatric population[14] because such pathology is commonly coincident with SIRVA.[6] Furthermore, alternative techniques of vaccination used in children, such as "bunching" of the subcutaneous tissue, may limit the risk of needle overpenetration.[3]

In addition to patient-specific factors, certain aspects of vaccination have been implicated in the development of SIRVA. In larger series, shoulder injury most commonly develops after injection of the influenza vaccine; reported rates of IIV-induced SIRVA vary between 62%[3] and 84%[4] of total cases. This is presumably because the IIV is the most commonly administered vaccine in the United States, with over 150 million doses given annually.[15] Other commonly associated vaccines include the tetanus, diphtheria, and pertussis (Tdap);[3,6] pneumococcal conjugate;[1,6] and recombinant zoster vaccines.[1] To date, no study has demonstrated an increased risk of SIRVA based on vaccine type.

By contrast, the vaccination technique may contribute markedly to shoulder injury. In an early series, 46% of SIRVA claimants reported vaccine administration "too high" in the deltoid.[3] This finding was replicated in a later series, in which 47.7% of patients alleged an error in administration, with 72.8% of these injections being "too high" or superior on the arm.[6] Although neither series quantified the definition of "too high" because it was related to patient perception, it is likely that excessively superior vaccine administration places the patient at a higher risk of penetration of the subacromial bursa or other underlying nonmuscular tissue. This, in turn, may initiate the theorized pathophysiological pathway that produces SIRVA-related symptoms.

Figure 1

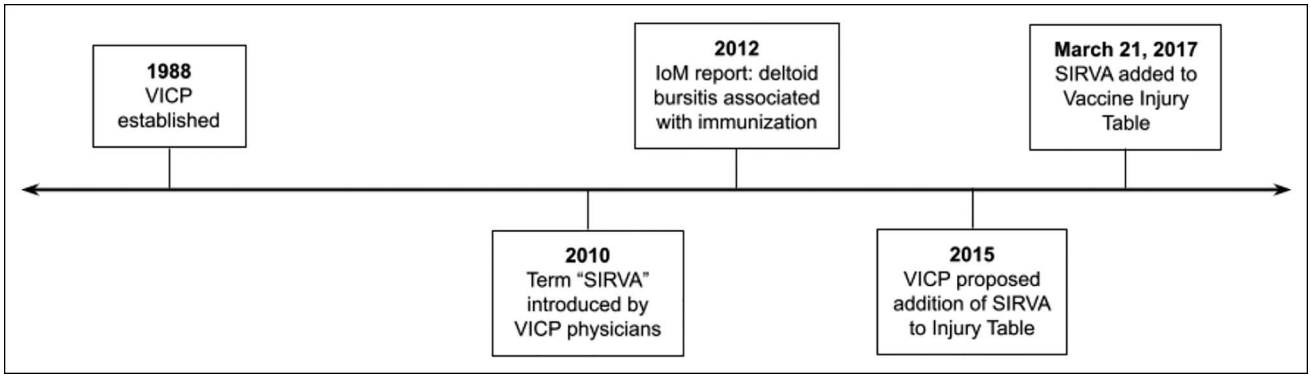


Chart showing the timeline of the addition of SIRVA to the VICP Vaccine Injury Table. IoM = Institute of Medicine, SIRVA = shoulder injury related to vaccine administration, VICP = Vaccine Injury Compensation Program

Finally, immunization in a pharmacy or free-standing clinic may portend an increased risk of SIRVA, with 35 to 41% of petitioners reporting vaccination in a similar location, compared with 6 to 30% reporting vaccination in a hospital or physician's office.[4,6] It is important to note that despite the associations implied by these observational studies, high-quality studies needed to determine causal relationships between specific risk factors and SIRVA are lacking.

Clinical Presentation

Broadly defined, SIRVA is a constellation of shoulder pain and reduced range of motion that occurs within 48 hours of vaccination and does not resolve within 1 week. Although this description encompasses nearly all musculoskeletal injuries that may result from injection, such a description makes it difficult to define SIRVA as a discrete clinical entity. As such, diagnosis at the time of primary evaluation varies widely; common initial diagnoses include rotator cuff pathology, bursitis, adhesive capsulitis, and neuritis.[6] This is compounded by the wide array of physicians to whom patients are referred after presentation with SIRVA-like symptoms. Approximately half of patients experiencing symptoms severe enough to file a VAERS report will seek evaluation by a healthcare practitioner; of these, nearly one-third will be referred to a specialist.[4] Hibbs et al[4] reported on 205 patients with SIRVA who underwent referral after initial evaluation; referral to an orthopaedic surgeon was most common (74%), followed by another surgeon (10%), chiropractor (6.8%), rehabilitation medicine physician (5.9%), or neurologist (4.4%).

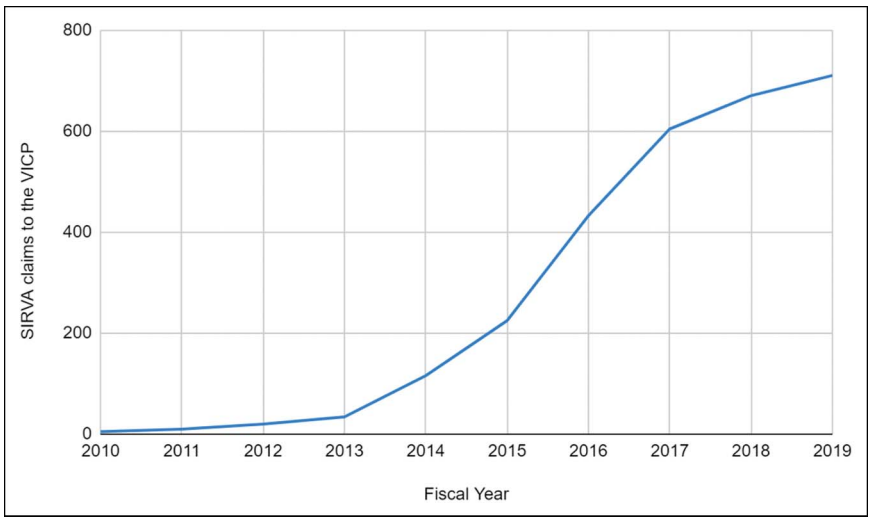
Despite orthopaedic referral being the most common among specialists, discussions of SIRVA remain scarce within the orthopaedic literature. Given the anticipated increase in SIRVA cases after mass distribution of the severe acute respiratory syndrome coronavirus 2 vaccine,[7] it is important for orthopaedic physicians to understand the appropriate evaluation of the patient presenting with shoulder dysfunction after vaccination. Evaluation begins with a thorough history and physical examination because diagnosis can often be confirmed in the absence of imaging.

History

The symptomatic hallmark of SIRVA is shoulder pain that occurs within 1 to 2 days of vaccination in a previously asymptomatic shoulder. Unlike shoulder pain that commonly occurs after vaccination, the pain associated with SIRVA does not resolve within 1 week. In one series, the onset of pain was noted within 24 hours of injection in 93% of patients, with 54% of patients reporting pain immediately after vaccination.[3] Hesse et al[6] reported a mean time from immunization to presentation of 15 days, despite the onset of pain typically occurring within 24 hours of vaccination.

In addition to pain, patients frequently describe limitations in range of motion (ROM). Hesse et al[6] found 31.1% of patients to report limited shoulder ROM after injection, whereas a second series found 40.8% of

Figure 2



Graph showing the SIRVA claims to the VICP by fiscal year, 2010 to 2019. SIRVA = shoulder injury related to vaccine administration, VICP = Vaccine Injury Compensation Program

Figure 3

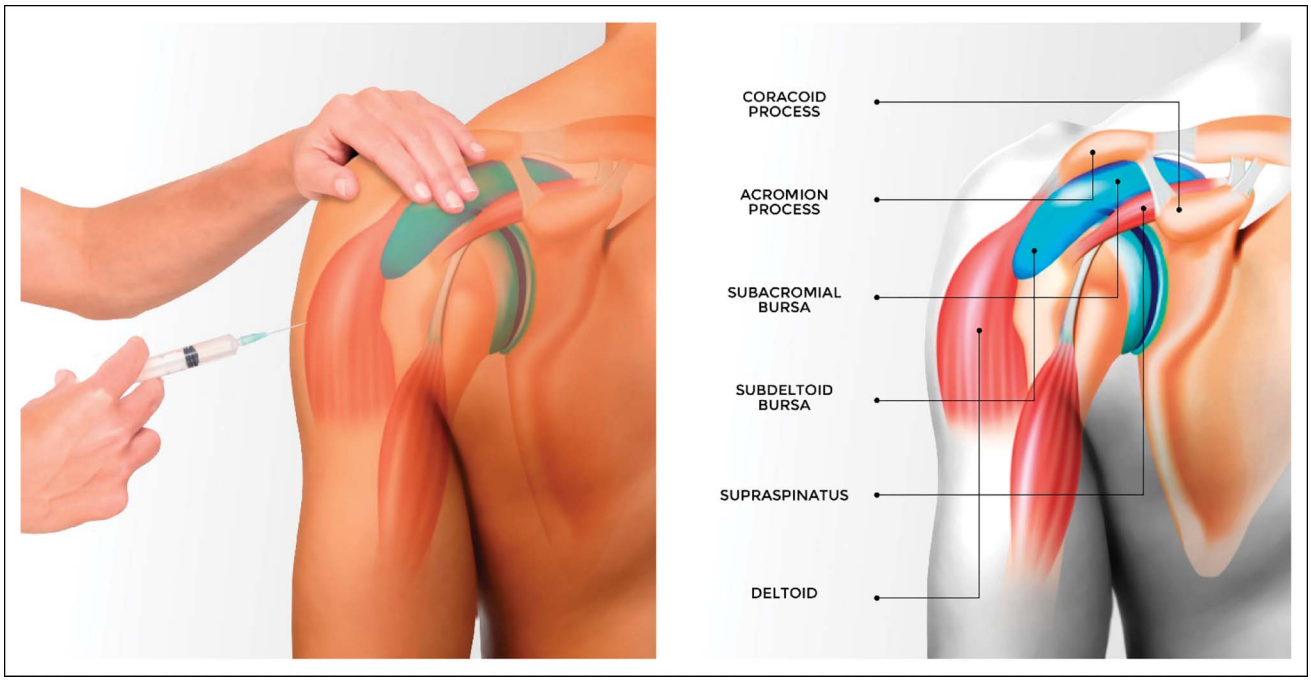


Illustration showing the anatomy of the shoulder girdle, including the causal relationships of the subdeltoid and subacromial bursae to the deltoid and joint space.

patients with SIRVA to report the limited mobility of the injected limb and 21.2% to report limited shoulder ROM.[4]

Because of pain and limited motion, patients may note difficulty performing the activities of daily living; 57.5% of VAERS reports reviewed by Hibbs et al[4] indicated that symptoms interfered with activities of daily living, whereas 22.5% of reports indicated absenteeism from work because of SIRVA symptoms. Patients may also express concerns regarding the improper vaccination technique, including excessively superior administration of vaccine, uneven positioning between the vaccinator and the patient, or difficulty with vaccine injection.[3,4,6] Frequently, patients report a history of previous vaccine administration without experiencing similar symptoms.[2,16] Although a minority of patients will describe neurologic symptoms, such as weakness, numbness, and paresthesias, these are uncommonly reported.[3,6]

Physical Examination

Examination of the patient presenting with shoulder pain after vaccination should include inspection, palpation, and a standard evaluation of ROM. The utility of provocative testing is unclear, but such testing may be useful in identifying associated or underlying pathology.[16] The most common findings of SIRVA on physical examination are globally limited and painful shoulder range of motion. Atanasoff et al[3] reported limited shoulder ROM in 85% of patients, whereas Hesse et al[6] noted limited ROM in 55.9% of patients. It is not apparent that specific motions exacerbate pain more severely than others because some case reports describe pain worse with flexion and abduction of the shoulder,[2] whereas others note pain worse with passive internal and external rotation.[16]

Tenderness to palpation of the injection site is also commonly encountered and was noted in 56.9% of petitioners by Hesse et al.[6] Neurological findings such as weakness and sensory loss are less common. An early series reported rates of 31% for both weakness and sensory loss,[3] whereas a larger series subsequently reported rates of 8.4% and 0.8%, respectively.[6] In the first series, all cases of weakness were attributed to pain rather than underlying neurological dysfunction.[3] When tested, deep tendon reflexes have been reported to be normal in patients with SIRVA.[2,3] Finally, skin and local injection site reactions are rare; reported rates vary between 0%[3] and 6.5%, respectively.[6]

Diagnostic Evaluation

Radiography, magnetic resonance imaging (MRI), and electrodiagnostic studies are commonly done, yet of

limited utility in the diagnosis of SIRVA. Because present series primarily comprise VICP claims or reports submitted to the VAERS, the current understanding of the diagnostic workup of SIRVA is limited to the medicolegal realm. Given the nonspecific symptoms associated with SIRVA and the broad array of diagnoses commonly assigned after initial evaluation, many patients undergo advanced imaging such as MRI to evaluate for soft-tissue pathology. Although MRI findings in SIRVA cases are generally nonspecific, such imaging can be useful in identifying concomitant and potentially contributory pathology.

Radiography

In retrospective analyses of petitioners with SIRVA to the VICP, routine shoulder radiographs are done in approximately half of the patients. Atanasoff et al[3] reported radiographs in 54% of petitioners, whereas Hesse et al[6] found radiographs in 55.7% of patients. In both series, the authors noted that radiographs provided little to no aid in the diagnosis of SIRVA.[3,6] Despite this, it is important to note the utility of routine radiography in the evaluation of a patient presenting with shoulder pain. The limitations of radiography in the diagnosis of SIRVA should not discourage orthopaedic surgeons from performing radiography in patients presenting with shoulder pain after vaccination because such pain may relate to other underlying pathology visible on radiograph.

Magnetic Resonance Imaging

In contrast to standard radiographs, MRI is done in 69%[3] to 80.7%[6] of patients with SIRVA. Although the pain associated with SIRVA often seems to be capsular or bursal in nature, MRI yields heterogeneous results that are typically reflective of preexisting pathology. When doing MRI, it is important for the surgeon to note the high incidence of structural anomalies that may be unrelated to vaccination. MRI may be useful in identifying concomitant and potentially symptomatic conditions within the shoulder, but it cannot be used to define a causal relationship between immunization and visualized pathology. The reported MRI findings in patients with SIRVA include tendinitis or tendinosis (49%), complete or partial rotator cuff tears (44%), fluid collections in the deep deltoid (39%), bursitis (34%), joint effusion (10%), muscle edema (9.6%), and bony edema (7.3%).[6] In one case report, a large lytic lesion developed in the proximal humerus after IIV injection.[17] Approximately 5% of MRIs are read as normal.[6] Atanasoff et al[3] reported that 63% of the MRIs done in their series were conducted within 3 months of symptom onset, whereas half were done within 6 weeks of symptom onset. Although based on the available literature, MRI does not seem to aid in the diagnosis of SIRVA, the identification of concomitant shoulder pathology can assist in guiding treatment.

Alternative Modalities

Alternative imaging and diagnostic modalities, such as electrodiagnostic testing and ultrasonography, have also been reported in the evaluation of SIRVA. In one series, 39% of patients with SIRVA underwent electrodiagnostic studies, none of which were suggestive of an underlying neurological disorder such as brachial neuritis.[3] Small case reports and series have also described the use of ultrasonography, although findings are generally nonspecific and suggestive of bursitis.[8,16] Thus, at this time, SIRVA remains a primary clinical diagnosis.

Treatment

The optimal treatment of SIRVA remains unclear because of the paucity of reported cases and limited understanding of the underlying pathophysiology. In most series, the mainstay of treatment consists of nonsteroidal antiinflammatory medications (NSAIDs), physical or occupational therapy, and corticosteroid injections (CSIs). In some cases, surgery is indicated to treat the underlying shoulder pathology.

The most prescribed initial treatment of SIRVA is physical or occupational therapy, with up to 80% of patients having at least one treatment visit.[3,4,6] NSAIDs are also frequently advised; Hibbs et al[4] found NSAID use reported in 46.5% of patients, whereas Hesse et al[6] reported NSAID use in 50.4% of patients. In addition to nonnarcotic analgesics, topical analgesics, such as lidocaine patches[2] and opioid medications, have been reported in a minority of patients.[6] Despite documented cases of opioid prescription for patients with SIRVA, the routine use of narcotics for the treatment of this condition is not recommended.

In addition to oral medications, two-thirds of patients with SIRVA receive corticosteroid injections into the subdeltoid, subacromial, or intraarticular space. However, the utility of this remains unclear.[3,6] In one case series, two patients diagnosed with SIRVA received CSI within 5 days of symptom onset and experienced symptom resolution within 1 month,[1] whereas in a second series, symptoms persisted for at least 6 months in all patients undergoing CSI.[3] Other reported conservative

Table 1. **Most Commonly Described Treatments of Shoulder Injury Related to Vaccine Administration**

Treatment	Study		
	Atanasoff et al[3] (N = 13), n (%)	Hibbs et al[4] (N = 546), n (%)	Hesse et al[6] (N = 476), n (%)
Physical or occupational therapy	6 (46)	215 (39)	381 (80)
Corticosteroid injections	8 (62)	109 (20)	286 (60)
NSAIDs or other analgesics	8 (62)	254 (47)	240 (50)
Oral steroids	NR	79 (14)	130 (27)
Narcotic analgesics	NR	28 (5.1)	65 (14)
Muscle relaxants	NR	15 (2.7)	29 (6.1)
Chiropractic treatment	NR	7 (1.3)	30 (6.3)
Acupuncture	NR	4 (0.7)	18 (3.8)
Surgery	4 (31)	16 (2.9)	155 (33)

NR = not reported, NSAID = nonsteroidal antiinflammatory medication

treatment modalities include oral steroids, chiropractic treatment, muscle relaxants, and acupuncture[6] (Table 1).

Given that all large series of patients with SIRVA are the retrospective reviews of VICP or VAERS petitioners, there currently exists no algorithm for the treatment of SIRVA, conservative, or otherwise. However, when conservative treatment fails, a subset of patients with SIRVA may require surgical intervention to address the underlying pathology noted on MRI or physical examination. The reported rates of surgical intervention vary; Hibbs et al[4] reported surgery in 2.9% of patients, whereas Hesse et al[6] noted surgery in 32.6% of petitioners. This discrepancy could be the result of differing patient populations because patients in the latter series were VICP petitioners seeking financial compensation for injury.

Surgical indications differ based on MRI and examination findings, and no single procedure is specific to the SIRVA population. Some of the more commonly done procedures include subacromial decompression (43.2% of surgeries), joint débridement (31.0%), rotator cuff repair (29.7%), synovectomy or bursectomy (16.1%), and manipulation under anesthesia (13.5%).[6] Despite multiple reports of surgical intervention for SIRVA in the literature,[3,4,6] no study has defined indications for the type of procedure done, nor reported outcomes of surgical versus conservative treatment.

Outcomes

The severity and duration of symptoms experienced by patients diagnosed with SIRVA varies widely. Although two case reports found complete resolution of symptoms within 1 month after CSI,[1,16] a third report noted persistence of symptoms at the final 8-month follow-up.[2] Of note, although the patient in the latter case was treated with NSAIDs and physical therapy, she did not undergo CSI. In a fourth case report, a patient developing a lytic lesion in the proximal humerus after IIV injection was treated with bone biopsy and subsequent arthroscopic débridement and experienced complete symptom resolution at the final 1-year follow-up.[17]

Despite the promising effects demonstrated by CSI in small case reports, the results in larger series are less favorable. In their early series of 13 patients, Atanasoff et al noted the persistence of symptoms beyond 6 months in all patients, including 8 patients undergoing CSI. Furthermore, less than one-third of patients experienced complete recovery at the final follow-up.[3] Similarly, in their more recent series of 476 patients, Hesse et al[6] noted the resolution of symptoms in only 24.3% of patients, with most of the patients experiencing residual symptoms, including pain, limited range of motion, weakness, and muscle atrophy. Notably, all patients in both studies were VICP petitioners seeking financial compensation for alleged SIRVA injury and may have been disincentivized to acknowledge the resolution of symptoms. However, in their review of patients with SIRVA submitting VAERS reports but not seeking financial compensation, Hibbs et al noted resolutions of symptoms in only 4.1% of patients at a median of 70 days after vaccination. Conversely, 86.6% of patients were found to have persistence of symptoms at the time of reporting; the authors were unable to comment on symptoms at the final follow-up.[4]

Taken together, the results of all published studies to date suggest only modest improvement in patients with SIRVA after both conservative and surgical treatment. Notably, all series have relied on self-reporting of recovery status and do not offer objective measures of clinical improvement. Furthermore, no series has compared outcomes in patients who file compensation claims versus those who do not. Finally, because no study has stratified outcomes based on treatment provided, it is not

currently possible to evaluate the relative efficacy of specific treatments for SIRVA. Additional high-quality studies are needed to determine the optimal treatment of this condition and factors predictive of outcomes.

Authors' Perspective

Although some authors have suggested that injection technique or antigen-antibody complex-related inflammation is responsible for SIRVA, there is no definitive evidence that this is the case. At this time, we think that SIRVA should be treated as a chronic, idiopathic inflammatory response within the deltoid muscle. In our experience, for most patients, SIRVA is relatively mild and self-limited and can be improved with local treatments or physical therapy. Unfortunately, in a small sample of patients, symptoms can be notable and long-lasting or permanent. Although it is possible for SIRVA to aggravate preexisting shoulder pathology seen on MRI or other diagnostic imaging, care should be taken before proceeding with surgical treatment for these conditions because they are often not the primary cause of the patient's symptoms. We have found the use of diagnostic lidocaine injections, especially useful in this population in differentiating symptoms related to vaccination-induced deltoid inflammation from other causes of shoulder pain. Despite the risk of SIRVA, given the notable personal and public health benefits of vaccinations, particularly in light of the coronavirus pandemic, we strongly recommend that patients receive vaccinations.

Summary

Despite the limited number of cases reported in the literature, annual data published by the VICP suggest that the incidence of SIRVA is increasing. Nevertheless, reports of SIRVA are limited to the medicolegal realm and consist primarily of patients filing compensation claims. Current theories implicate the formation of antibody-antigen complexes within the subacromial or synovial space, yet available data are limited to small case series and animal studies. Although many patients presenting with shoulder pain after vaccination will undergo radiographic and advanced imaging studies, SIRVA remains a primarily clinical diagnosis. Treatment modalities, such as physical therapy and corticosteroid injection, do impart some functional benefit, but a notable number of patients seem to have persistent pain and functional limitation after diagnosis. Additional high-quality studies, including clinical series of nonclaimant patients, are needed to elucidate the natural history and optimal treatment of this increasingly common condition.

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