

# Shoulder Injury Related to Vaccine Administration: Case Series

## *Lesão de ombro relacionada à administração de vacina: Série de casos*

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Rev Bras Ortop 2023;58(2):279–283.

### Abstract

**Objective** Shoulder pain is a common presentation in the primary care setting, and shoulder pain after vaccination has a growing body of literature. The present study sought to understand how a standardized treatment protocol would aid patients experiencing shoulder injury related to vaccine administration (SIRVA).

**Methods** Patients experiencing SIRVA were retrospectively recruited between February 2017 and February 2021. All patients were treated with physical therapy and offered a cortisone injection. Post-treatment range of motion (i.e., forward elevation, external rotation, internal rotation) and patients' reported outcomes were collected with the visual analogue scale (VAS), American Shoulder and Elbow Surgeons (ASES), simple shoulder test (SST), and single assessment numeric evaluation (SANE) scores.

**Results** A total of 9 patients were retrospectively examined. Among them, 6 patients presented within one month of a recent vaccination event, while 3 patients presented 67, 87, and 120 days after vaccination. Furthermore, 8 of the patients completed physical therapy, and 6 of them underwent a cortisone injection. The follow-up time averaged 8 months. At final follow-up, the mean external rotation was 61° (standard deviation, SD ± 3°) and the mean forward elevation was 179° (SD ± 45°). Internal rotation ranged between L3 and T10. The VAS pain scores were 3.5/10.0 (SD ± 2.4), the mean ASES score was 63.5/100.0 (SD ± 26.3), and the SST scores were 8.5/12.0 (SD ± 3.9). Finally, the SANE scores were 75.7/100.0 (SD ± 24.7) and 95.7/100.0 (SD ± 6.1) in the injured and contralateral shoulders respectively.

**Conclusion** Shoulder pain after a vaccination treated with physical therapy and cortisone injection ultimately resulted in favorable shoulder range of motion and functional score outcomes.

**Level of Evidence** IV.

### Keywords

- ▶ bursitis
- ▶ pain management
- ▶ rotator cuff injuries
- ▶ shoulder injuries
- ▶ vaccination

*Work developed at the Department of Orthopedic Surgery, Icahn School of Medicine at Mount Sinai, New York, NY.*

received  
November 24, 2021  
accepted  
May 16, 2022  
article published online  
July 1, 2022

DOI <https://doi.org/10.1055/s-0042-1751022>.  
ISSN 0102-3616.

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## Resumo

**Objetivo** A dor no ombro é um quadro comum na atenção primária e há cada vez mais relatos acerca de sua ocorrência após a vacinação. Este estudo buscou entender como um protocolo de tratamento padronizado ajudaria pacientes com lesão no ombro relacionada à administração de vacina (SIRVA).

**Métodos** Os pacientes com SIRVA foram recrutados de forma retrospectiva entre fevereiro de 2017 e fevereiro de 2021. Todos os pacientes foram submetidos à fisioterapia e receberam uma prescrição de cortisona injetável. A amplitude de movimento pós-tratamento (ou seja, elevação anterior, rotação externa, rotação interna) e os desfechos relatados pelo paciente foram analisados a partir das pontuações da escala visual análoga (EVA), da American Shoulder and Elbow Surgeons (ASES), do teste simples do ombro (SST) e da avaliação numérica única (SANE).

**Resultados** No total, 9 pacientes foram examinados de maneira retrospectiva. Entre eles, 6 pacientes foram atendidos no primeiro mês após a vacinação e os outros 3 depois de 67, 87 e 120 dias. Ademais, 8 dos pacientes fizeram todo o tratamento fisioterápico e 6 receberam uma injeção de cortisona. O período médio de acompanhamento foi de 8 meses. À última consulta, a rotação externa média foi de 61° (desvio padrão, DP ± 3°) e a elevação anterior média foi de 179° (DP ± 45°). A rotação interna variou entre L3 e T10. As pontuações de dor à EVA foram de 3,5/10,0 (DP ± 2,4) e o escore médio ASES foi de 63,5/100,0 (DP ± 26,3); as pontuações de SST foram 8,5/12,0 (DP ± 3,9). Por fim, os escores de SANE foram de 75,7/100,0 (DP ± 24,7) e 95,7/100,0 (DP ± 6,1) nos ombros lesionados e contralaterais, respectivamente.

**Conclusão** A dor no ombro após a vacinação tratada com fisioterapia e injeção de cortisona melhorou a amplitude de movimento e os escores funcionais.

**Nível de Evidência** IV.

## Palavras-chave

- ▶ bursite
- ▶ manejo da dor
- ▶ lesões do manguito rotador
- ▶ lesões do ombro
- ▶ vacinação

## Introduction

The prevalence of general shoulder pain in the primary care setting has been reported to range from 6 to 26%.<sup>1,2</sup> Shoulder injury related to vaccine administration (SIRVA) was originally reported by Bodor in 2007, but accounts of SIRVA have rapidly expanded since.<sup>3-21</sup> The primary mechanism of action theorized to cause a SIRVA is vaccination needle overpenetration of the deltoid muscle. Resulting injuries are thought to be caused by mechanical trauma of the needle and/or an immune response stimulated by the vaccine contents or adjuvants.<sup>3-21</sup> Although the exact mechanism has not been proven, SIRVA has been reported to cause injury to the rotator cuff, bursa, the labrum, and the shoulder capsule, and commonly reported resulting sequel have included bursitis, adhesive capsulitis, rotator cuff tears, chondral injuries and nerve injuries.<sup>3-21</sup>

Shoulder injuries related to vaccination events have been recorded and documented by the Vaccine Adverse Event Reporting System since 1990, and this is monitored by the Center for Disease Control.<sup>22</sup> It was not until 2011 that the Institute of Medicine provided updates to the Vaccine Injury Table. This table now states several criteria that must be met for a shoulder injury after a vaccination to be a SIRVA. These criteria include pain within 48 hours of the vaccination, no prior history of shoulder pain or dysfunction, pain and reduction shoulder range of motion

and no other condition that can explain the symptoms.<sup>23-25</sup>

Despite the importance now placed on these types of injuries and the worldwide increase in vaccinations, there is a paucity of data reporting patient outcome with shoulder pain after a vaccination, and to date there has been no cohort treated with a standardized treatment plan. Thus, the primary outcome measure of this analysis is to report on a series of individuals presenting with acute shoulder pain after a vaccination all treated with a standardized protocol.

## Materials and Methods

The institutional review board at our institution approved this study. This is a retrospective study of patients who presented with pain following vaccination between February 2017 and February 2021. Patients were treated based on clinical presentation and shoulder radiographs, and MRI was used when patients presented with refractory symptoms. The inclusion criterion was shoulder pain following vaccination, and the exclusion criteria were prisoners and individuals under 18 years of age. Shoulder function and range of motion (i.e., forward elevation, external rotation, internal rotation) were evaluated at a final follow-up visit by a fellowship-trained orthopedic surgeon using a goniometer. Demographic information such as age, gender, body mass index (BMI), and

smoking status were recorded. Function was assessed using the Simple Shoulder Test (SST) and the American Shoulder and Elbow Surgeons (ASES) score. Satisfaction was assessed using the Single Assessment Numeric Evaluation (SANE) score. Pain was assessed using the Visual Analog Scale (VAS) score. Internal rotation was measured using vertebral levels. All patients were offered or had previously participated in a course of physical therapy. Additionally, all patients were offered a corticosteroid injection.

## Results

### Study Population

The study identified 14 patients who presented for shoulder pain following a vaccination. However, 5 patients were excluded as they were lost to follow-up. The vaccinations reported to have preceded the symptoms were influenza ( $n = 5$ ), shingles ( $n = 2$ ), coronavirus disease of 2019 (COVID-19,  $n = 1$ ), and human papillomavirus (HPV,  $n = 1$ ). Patients presented with bursitis ( $n = 9$ ), biceps tendinitis ( $n = 6$ ), intramuscular phlebitis ( $n = 1$ ), and superior glenoid labrum lesion ( $n = 1$ ).

A total of 9 patients were included, all experiencing shoulder pain after receiving a vaccination; 3 of them on the left shoulder and 6 on the right shoulder. The mean age was 58.7 years ( $SD \pm 14.0$ ; range 33–82) with 1 male and 8 females. The mean time from vaccination to onset of pain was 15 hours; 8 patients reported onset of pain and symptoms within 24 hours while 1 patient reported pain onset occurring within 48 hours of vaccination. The mean time from onset of pain to initial visit was 43 days ( $SD \pm 6.2$ ; range 7–120). The mean time from onset of pain to last follow-up visit was eight months ( $SD \pm 13.0$ ; range 1–42). The mean BMI was 25.1 ( $SD \pm 4.6$ ; range 19–33). Regarding smoking status, 5 patients had never smoked before, 1 patient was a current smoker, and 3 patients were former smokers. The former smokers had quit smoking on average 29 years ( $SD \pm 10.6$ ; range 21–41) prior to their visit. Furthermore, 5 patients received corticosteroid injections and 8 patients attended physical therapy. Finally, 1 patient underwent arthroscopic superior labral repair and arthroscopic subacromial decompression following a failure of the course physical therapy and cortisone to resolve symptoms.

### Clinical Outcomes

At the initial visit, the mean external rotation was  $60^\circ$  ( $SD \pm 0^\circ$ ). The mean forward elevation was  $180^\circ$  ( $SD \pm 0^\circ$ ). Internal rotation ranged from L3 and L1, and in all cases was similar to the contralateral side. At the final follow-up, the mean external rotation was  $61^\circ$  ( $SD \pm 3^\circ$ ). The mean forward elevation was  $180^\circ$  ( $SD \pm 0^\circ$ ). Internal rotation ranged between L3 and T10, and in all cases was similar to the contralateral side. The mean VAS pain score was 3.5 ( $SD \pm 2.4$ ), the mean ASES score was 63.5 ( $SD \pm 26.3$ ), and the SST scores were 8.5 ( $SD \pm 3.9$ ). Mean SANE scores in the affected shoulder were 75.7 ( $SD \pm 24.7$ ) and 95.7 ( $SD \pm 6.1$ ) in the contralateral shoulder. The patient who underwent a superior labral repair and subacromial decompression reported no pain and resolution of function.

## Discussion

The most common shoulder issues after a vaccination are pain and loss of range of motion.<sup>3–21</sup> In this study, both common sequels were addressed with physical therapy and in most cases a corticosteroid injection. The thought process behind this treatment plan was to improve or prevent loss of shoulder motion with an organized physical therapy protocol. The corticosteroid injection was added for the benefit of addressing inflammation that may have been caused by an immune response to the vaccine or vaccine adjuvants.

All patients were offered this treatment, but compliance with physical therapy occurred in 8 patients and only 6 patients decided to undergo a cortisone injection. Despite the variance from these two modalities, ultimate range of motion and pain assessments were good. Forward elevation, external rotation and internal rotation values were nearly identical in the majority of patients and were at the limits of normal range of motion values. The mean VAS pain score averaged 3.5 in 10, and the mean ASES score was of 63 in 100. For SST scores, the average was of 8.5 in 12. In a previous multispecialty study, the mean VAS score for patients satisfied with recovery was of 24 in 100 ( $SD \pm 20$ ), and 45 in 100 ( $SD \pm 27$ ) for patients who were unsatisfied or not sure how to rate their recovery.<sup>26</sup> In another study, Sciascia et al.<sup>27</sup> observed that the minimum score for satisfied patients was of 78 in 100 for ASES and 58 in 100 for SANE. In an earlier, large-scale study evaluating 1,077 shoulders, it was noted that the mean SST score for patients under 60 years old was 7.1.<sup>28</sup> Based on these findings, our patients reported above average scores for patient satisfaction (SANE), moderate pain levels, and average to above average shoulder function (ASES and SST, respectively).

The vast majority of SIRVA reports have been documented as case reports or small case series, and a recent systematic review demonstrated only three publications included more than three patients.<sup>29</sup> The largest of those three studies was conducted by Anasoff et al.,<sup>4</sup> in which the results of 13 patients were reported; the results were derived from the Vaccine Injury Compensation Program Database. Thus, it is very likely this was obtained from a series of different care providers. The time between vaccination and clinical presentation, representing the time between injury and treatment, was not provided, and patients were treated with nonsteroidal anti-inflammatory pain medications, physical therapy, steroid injections, and surgery. Thus, a standardized treatment plan and treatment onset could not be identified.

In a slightly smaller study, Martín Arias et al.<sup>13</sup> reported 8 patients treated for a shoulder injury after vaccination. Similar to the paper by Anasoff et al.,<sup>4</sup> Martín Arias et al.<sup>13</sup> obtained the patients from a database. They utilized the Spanish Pharmacovigilance System database. The time between vaccination and treatment initiation was also unknown and, in this case, the treatments provided were not reported.

In a different study, Okur et al. reported the results of 4 patients between 5 months and 2.5 years following vaccination.<sup>15</sup> The primary focus of this study was magnetic

resonance imaging findings, and treatments and follow-up time points were not controlled.

Thus, our study represents one of the largest datasets of patients with pain after a vaccination and, more importantly, this study represents the largest dataset made up of patients treated with a uniform protocol.

Although the data presented suggests physical therapy and a cortisone injection may lead to improved clinical outcomes and prevention of shoulder stiffness, there are several limitations to this study. First, although physical therapy and a cortisone injection were offered to all patients, compliance was not perfect. But with 8 of 9 patients complying with a physical therapy protocol, we feel adequate compliance was met to make an association. By nature of being a retrospective study, a prospective comparison group is not available. A separate, randomized group treated with a different modality or simple observation would increase the validity of the associations appreciated. Finally, although this represents one of the largest collections of patients with shoulder pain after vaccination, our sample size is still small and, thus, could result in sampling bias.

## Conclusions

In conclusion, our data represents the largest, to date, collection of patients treated by a single provider with a uniform treatment algorithm. Our data suggests that an intervention with physical therapy and the possible addition of a corticosteroid injection correlates with good shoulder range of motion, prevention loss of range of motion in the affected shoulder, and maintenance of shoulder function at an average of 8 months of follow-up. Additional large-scale, randomized data are still needed to understand how to best treat patients who present with shoulder pain after a vaccination.

### Financial Support

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

### Conflict of Interest

Paul J. Cagle, MD  
Stryker: Consultant

Johnson & Johnson: Consultant

The following individuals have no conflicts of interest or sources of support that require acknowledgment: Christopher A. White and Akshar V. Patel.

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