SIRVA

SIRVA: Shoulder Injury Related to Vaccine Administration

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ABSTRACT

Shoulder Injury Related to Vaccine Administration (SIRVA) is a prolonged episode of shoulder dysfunction that commences within 24 to 48 hours of a vaccine immunisation injection. Symptoms include a combination of shoulder pain, stiffness and weakness. There has been a recent rapid increase in reported cases of SIRVA within the literature, particularly in adults, and is likely related to the mass immunisation programmes associated with COVID-19 and influenza. The pathophysiology is not certain, but placement of the immunisation in the subdeltoid bursa or other pericapsular tissue has been suggested to result in an inflammatory capsular process. It has been hypothesised that this is associated with a vaccine injection site that is "too-high" and predisposes to the development of SIRVA. Nerve conduction studies are routinely normal, but further imaging can reveal deep-deltoid collections, rotator cuff tendinopathy and tears or subacromial subdeltoid bursitis. However, all of these are common findings within a general asymptomatic population. Medicolegal claims in the UK, based on an incorrect injection site, are unlikely to meet the legal threshold to determine liability.

INTRODUCTION

Although mild, self-limiting, shoulder pain has been widely recognised as a short term side-effect of intra-muscular vaccination around the shoulder, the entity of Shoulder Injury Related to Vaccine Administration (SIRVA) describes a prolonged episode of shoulder dysfunction that has an onset within 24 to 48 hours of immunisation. It manifests as a combination of shoulder pain, stiffness and/or weakness. SIRVA was first defined as a clinical entity in 2010 by Atanasoff et al in an examination of the database of the United States Vaccine Injury Compensation Scheme (VICP).[1] Since then there are now 55 papers indexed in PubMed (https://pubmed.ncbi.nlm.nih.gov) related to SIRVA (search date 22 March 2023). The majority have been published from 2020 onwards (n=46, 84%) (Figure 1). This is likely related to a significant increase in the number of mass immunisation programmes focusing on COVID-19 and influenza.

The original published series identified 13 patients from the VICP database.[1] This programme was implemented to introduce a no-fault compensation scheme in the US to redirect patients away from the traditional medicolegal routes of recompense. The profile of claimants has changed over time from mostly paediatric to adult based claims.[1] The original series reported immunisation mostly with influenza vaccines and one case of tetanus immunisation and highlighted the concept of the injection being self-reported by the claimant as being placed "too-high" on the upper arm. While nerve conduction studies were universally normal, there were a variety of imaging findings including deep-deltoid collections, rotator cuff tendinopathy and tears, and subacromial subdeltoid bursitis (although the latter two are frequently found in the general population). Atanasoff et al referred to the earlier work of Bodor et al[2] who described shoulder dysfunction following vaccination in two patients following influenza and pneumococcal vaccination respectively. A follow-up study of the VICP database was published in 2020 and reported 476 claims from 2010 to 2016 related to SIRVA. A recent

review of database of adverse events in Australia recorded 221 cases following COVID-19 immunisation over a one-year period from February 2021 onwards.[3] In this series the person receiving the vaccination self-reported that they felt the injection was administered too high in the arm in 75.5% of cases.

PATHOPHYSIOLOGY

The pathophysiology of SIRVA is likely to consist of several overlapping processes. The most common described pattern is that of pain and stiffness consistent with frozen shoulder (FS: adhesive capsulitis).[4–6] Placement of the immunisation in the subdeltoid bursa or other pericapsular tissue has been postulated to result in an inflammatory capsular process. Other studies have suggested a subacromial subdeltoid bursitis as the primary pathology,[7–13], whilst there have also been case reports of calcific tendonitis.[14,15] Where there is isolated evidence of neuropathic changes in the axillary or radial nerve there may be underlying iatrogenic damage due to inferior needle placement.[16,17] Diffuse weakness and neuropathic changes in non-dermatomal and myotomal patterns may indicate a brachial neuritis aetiology (Parsonage-Turner Syndrome)[6,18–20]. A case report also exists of isolated infraspinatus myositis.[21] A variety of radiological structural changes have been reported including calcification, degeneration and rotator cuff tears.[8] Caution needs to be exercised in automatically linking a structural imaging abnormality with the causation of SIRVA as these findings can be present in the general population without corresponding symptomatology.

INJECTION TECHNIQUE AND CAUSATION

Injection techniques rely on a landmark based procedure and emphasise importance of location in order to avoid placement in the subacromial subdeltoid bursa, as well as avoiding neurovascular injury to particularly the axillary nerve or posterior humeral circumflex artery.

There is less known or reported about appropriate depth of injection, but accurate intramuscular placement will depend on the length of needle, as well as the size of the adipose layer and the underlying deltoid muscle. Inadvertent injection into the bursa would be more likely with a longer needle in thinner patients with less muscle mass.

It has been hypothesised that an injection site "too-high" may predispose to the development of SIRVA.[22,23] The standard teaching for a shoulder intramuscular injection is to inject in the midline of the lateral aspect of the upper arm, one to three fingers breadths below the edge of the acromion. This is to avoid injection through the deltoid and into the underlying bursa. It also avoids the complication of injury to the neurovascular structures. Recent research has reported evidence-based advice regarding administration.[24] It has recommended that, due to the documented variation in the course of the axillary nerve, injection should be given at least 7.4cm beyond the edge of the acromion to avoid damage to the axillary neurovascular bundle by allowing placement inferior to the nerve (Figure 2). Positioning of the shoulder with abduction to 60 degrees is important as this moves the axillary nerve more proximally. No study has attempted to correlate patients' reports of vaccine site with actual placement, and the development of subsequent symptoms. Therefore, there is no evidence as to the accuracy of this self-reported subjective observation. Given the patient's point of view and perspective it is difficult to judge distance and few patients would be experienced enough themselves in the anatomical basis for an intramuscular injection technique.

MEDICOLEGAL IMPLICATIONS

While programmes such as the VICP exist in the US to provide no-fault compensation for vaccine related injury and thereby reduce the medicolegal costs associated with a traditional system, there is no such system in the United Kingdom.[1,25] Liability in the UK would rest with the organisation undertaking vaccination, with an individual immuniser being covered by the

employer's vicarious liability. A claim for injury caused by a vaccine would come under civil litigation covering medical negligence. This would require both causation and liability to be proved. In terms of causation, a sudden onset of shoulder dysfunction following vaccination is, on the balance of probabilities, linked to the administration of the vaccination and that but for the vaccination the patient would not have suffered the symptoms and limitations reported.

It is more difficult to prove liability in claims for medical negligence. In England the Bolam Test is used to determine if clinical negligence has occurred.[26] A clinician must have acted out with the actions deemed reasonable by a responsible body of professional opinion. A similar test is applied in Scotland, called the Hunter v Hanley Test.[27] It must be established that there is a usual and normal practice, that the practice was not adopted, and that the actions taken were such that no professional of ordinary skill would have taken if acting with ordinary care. In most cases it would be impossible to accurately identify the exact location of the injection retrospectively. It would also be not possible to rely on the claimant's opinion of placement of the vaccine, given their likely lack of training in the matter and their perspective of observation. If the vaccination was performed by an immuniser acting in accordance with demonstrable training and standard operating procedures, it would seem not possible to prove negligence due to an allegation of an injection site alone. Furthermore, although there is speculation that misplacement in the bursa is a potential cause, there are other plausible mechanisms and SIRVA is a diagnostic umbrella covering several entities. Injection within the anatomical bounds of what is currently considered safe could still lead to inadvertent injection of the bursa below the deltoid muscle. For liability to be proved there would have to be another significant departure from normal practice around the time of immunisation. Thus, it is unlikely that claims based on an allegation of mispositioning of the injection site could succeed in most circumstances. Where no-fault compensation schemes such as VICP exist, there is no onus to prove liability and the determination of compensation is based on pre-determined protocols.

CONCLUSIONS

SIRVA, having been originally described in a small number of cases in 2010, is increasing in both incidence due to mass vaccination campaigns, as well as recognition due to the increasing research publications. The symptomatology can cover several different shoulder conditions. Diagnosis is important to target treatment to the specific presenting condition. Further work is required to define the safe boundaries of injection in the upper arm and translate this to education of clinicians providing immunisations. Medicolegal claims in the UK based on an incorrect injection site are unlikely to meet the legal threshold to determine liability.

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Figure Legends

Figure 1: Number of papers cited per year, since 2010, in PubMed database with “SIRVA” in title or abstract.

Figure 2: Lateral view of shoulder and deltoid area highlighting structures at risk during intramuscular injection. These are avoided through a combination of shoulder abduction to 60 degrees and injection at least 7.4cm from the edge of the acromion (Created with BioRender.com)