



Case report

Ultrasonic aspiration for vaccination-related shoulder dysfunction

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ABSTRACT

Background: Chronic shoulder pain occurs rarely after a vaccination and is hypothesized to arise from the effects of unintentional vaccine injection into the subacromial bursa, rotator cuff, capsule or underlying bone. The avascular nature of the rotator cuff, as well as unknown genetic and environmental factors, may predispose to the persistence of pain and disability, referred to as vaccination-related shoulder dysfunction and shoulder injury related to vaccine administration (SIRVA).

Methods: Ultrasonography, sonopalpation and ultrasound-guided anesthetic injections were used to locate the anatomical source of chronic (mean 20, range 8–42 months) shoulder pain after a vaccination in a consecutive series of 5 patients. Subsequently ultrasound-guided ultrasonic aspiration and debridement was performed using a 2.1 mm outer cannula with an inner needle vibrating at 28 kHz. Outcomes were assessed using the Quick Disabilities of the Arm, Shoulder and Hand (QDASH) scale at 2, 4, 12, 24 weeks and 1 year.

Results: The distal infraspinatus and teres minor tendons, their insertions and or the adjacent bone were the source of pain in all 5 patients. The mean QDASH score improved from 65 points to 11 points at 2 weeks ($P = 0.001$), and to 1 point at 4 weeks after the procedures ($P = 0.003$). Improvements in pain and function remained stable at 1 year in 3 patients, for at least 24 weeks in 1 patient who died of unrelated causes, and 1 year in 1 patient for posterior shoulder pain who after a pain free interval developed anterior shoulder pain related to his previously asymptomatic osteoarthritis ($P = 0.013$).

Conclusion: The distal infraspinatus and teres minor tendons, their insertions and adjacent bone are a common source of chronic shoulder pain after a vaccination. Ultrasound-guided ultrasonic aspiration and debridement is a potentially effective treatment for resolving pain and restoring function.

1. Introduction

Chronic shoulder pain occurs rarely after a vaccination and is hypothesized to arise from the effects of unintentional vaccine injection into the subacromial bursa, rotator cuff, capsule or underlying bone [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]. The avascular nature of the rotator cuff and capsule, as well as unknown genetic and environmental factors, may predispose to the persistence of shoulder pain and disability, referred to as vaccination-related shoulder dysfunction and shoulder injury related to vaccine administration (SIRVA).

In a population cohort study of almost 3 million vaccinations, Hesse et al [11] found that the excess risk of shoulder bursitis during the first 2

days after an influenza vaccination is 7.8 cases per million. Given over 300 million vaccinations per year in the United States [12], this should result in approximately 2500 new cases per year. Hesse et al [11] searched only for cases of bursitis and not rotator cuff tendinitis or other diagnoses. Out of the 1220 cases of shoulder pain after influenza injections reported to the Vaccine Adverse Event Reporting System between 2010 and 2017, 87% involved chronic pain and disability [6]. SIRVA is the most common disabling complication resulting from a vaccination based on the number of claims filed at the National Vaccine Injury Compensation Program [13].

Magnetic resonance imaging (MRI) has shown subacromial-subdeltoid bursitis, rotator cuff edema, adhesive capsulitis and

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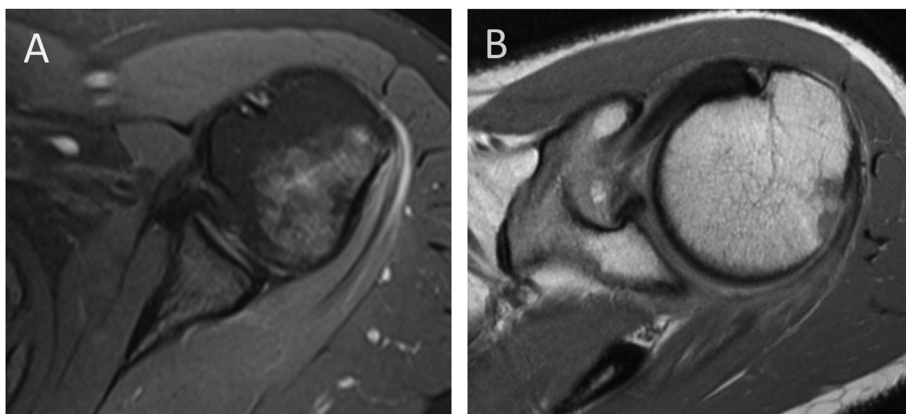


Figure 1. (A) Axial T2-weighted fat-suppressed MRI 2 months after an influenza vaccination showing edema in the teres minor tendon and posterior humerus. After 3 years the edema resolved, but the pain persisted (from Natanzi et al. [10]). (B) Axial T1-weighted MRI 2 months after an influenza vaccination showing edema in the infraspinatus tendon and lytic lesions in the posterior humerus, which enlarged into a single lesion over the next 8 months. Following surgical debridement of the lesion, the patient's pain resolved (from Erickson et al. [14]).

progressive lytic lesions of bone (Figure 1A,B) [8, 9, 10, 14]. In surgically treated cases, findings have included chronic bursitis (Figure 2), rotator cuff tendinopathy and lytic lesions of bone [14, 15, 16, 17]. Histologic analysis has shown papillary hypertrophy and lymphoplasmacytic inflammation of the capsule, synovium, cartilage and bone [14, 17]. Various treatments have been tried including non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, physical therapy, distention arthrography and surgery, but many patients have ongoing pain and disability [2]. For these patients, up until now, there has been no specific diagnostic method or treatment technique.

Our goal was to be able to precisely diagnose the source of chronic shoulder pain after a vaccination and perform a treatment to resolve pain and restore function. We present a series of 5 patients diagnosed via a specific method and treated using ultrasonic aspiration and debridement, a technique used for the treatment of chronic tendinopathies [18, 19, 20, 21].

2. Materials and methods

2.1. Patients and setting

The setting is a private physical medicine and rehabilitation clinic with research and teaching affiliations with two academic medical centers. All procedures were performed by the first author. Patients provided informed consent for their procedures and publication of their case histories. Prospective data collection and analysis was approved by our local hospital institutional review board.

The cases consisted of 5 consecutive patients (4 women and 1 man), mean age 59 years (range, 33–69), presenting to our clinic via physician or self-referral between January 2018 and October 2019 (Table 1). Patients were included if they had no prior pain in the affected shoulder, experienced onset of shoulder pain with the vaccination, had pain for at least 6 months and had tried other treatments without lasting improvement. The mean duration between the onset of symptoms and the ultrasonic aspiration and debridement procedures was 20 months (range 8–42 months). The first patient was informed that the technique had been used before for tendinopathies, but not specifically for this indication. Subsequent patients were informed of the outcomes of previous patients.

The primary outcome measure was improvement in pain and function as assessed by the Quick Disabilities of the Arm, Shoulder and Hand (QDASH) 11-item scale (Appendix A). One of the investigators not treating the patients (YU) performed the preoperative assessments, sent and received all of the QDASH forms or telephoned patients to assess their outcomes at 2, 4, 12, and 24 weeks, and 1 year.

2.2. Diagnostic ultrasonography, sonopalpation and anesthetic injections

Comprehensive musculoskeletal ultrasonography (Philips iU-22, 12.5 and 17.5 MHz transducers) of the shoulder, a validated technique for the detection of rotator cuff disorders [22, 23, 24], was performed according to established protocols [25, 26]. Each patient was asked to point with one finger where they were maximally tender. This location was carefully scanned and assessed for rotator cuff tendon tears, abnormal echotexture and cortical bone abnormalities, which can be differentiated from nutrient foramina based on the absence of vascular flow on Doppler ultrasound. Sonopalpation was performed using the ultrasound transducer, the sonographer's little finger or the tip of a curved hemostat placed under the transducer to precisely identify which anatomical structures were tender. Subsequently, the suspected pain generator was injected with 0.5–1.0 ml of 4% lidocaine (Hospira Inc., Lake Forest, IL). If two structures on top of each other (e.g. a tendon and an underlying bone defect) were suspected to be pain generators, then both structures were anesthetized with the total volume of anesthetic being limited to 0.5–1.0 ml. If there was a 50% or greater reduction of pain, the location was noted and the patient was scheduled to undergo an ultrasonic aspiration and debridement procedure.

2.3. Ultrasonic aspiration and debridement

At an outpatient surgery center, the patient was taken to the operating room and placed in a side-lying position with the affected shoulder facing up. Ultrasonography (Esaote Mylab 25 Gold, 10–18 MHz transducer) was used to locate the previously identified source of pain. After sterile preparation for surgery using 2% w/v chlorhexidine gluconate and 70% v/v isopropyl alcohol, the skin, subcutaneous tissues, and affected area of the rotator cuff, capsule and underlying bone were anesthetized with 2–3 ml of a 50:50 mixture of 4% lidocaine and 0.5% ropivacaine (Hospira Inc, Lake Forest, IL). An incision was made through the skin and fascia of the deltoid muscle with a number 11 scalpel blade, followed by insertion of the 2.1 mm ultrasonic aspiration cannula containing an inner needle that vibrates back and forth at 28 kHz when activated (TX2, Tenex Health, Lake Forest, CA). Using ultrasound-guidance, the tip of the cannula with its inner needle were guided into position within the rotator cuff and capsule and to any bone defects.

Once activated the device was advanced and withdrawn back and forth in a systematic fashion for several minutes to treat an approximately 0.5–1.0 cm³ volume of tendon and bone. The tip of the cannula was visualized in multiple orthogonal ultrasound planes to ensure a thorough debridement. Microbubbles caused by device-induced cavitation accumulated in treated areas, as did minute fragments of tendon and bone in the fluid collection bag. The treatment was complete once the tip of the cannula had been passed through all of the targeted tissue or there

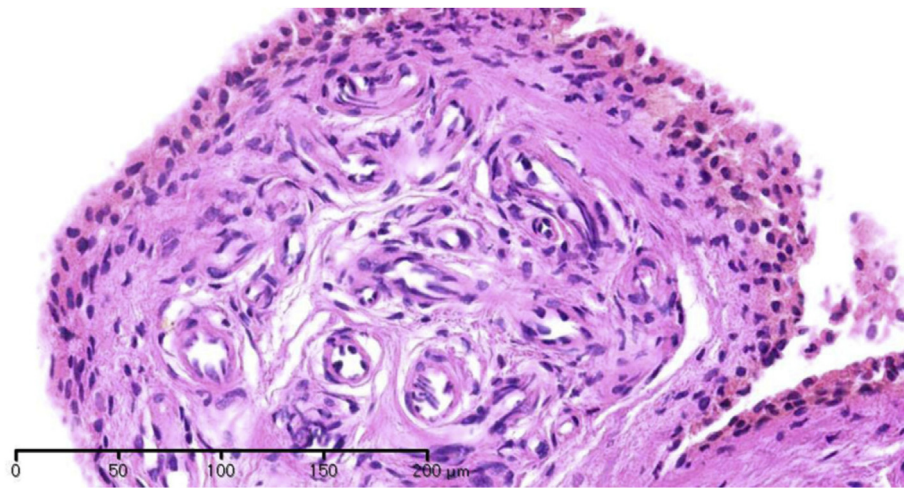


Figure 2. Histologic examination showing inflammatory infiltrate and granulation tissue with mild fibrosis, suggestive of chronic bursitis in a patient with chronic shoulder pain after a human papilloma virus vaccination (from Uchida et al. [17]) Following arthroscopic synovectomy, the patient experienced rapid resolution of pain and restoration of function.

Table 1. Patient information, age, sex, vaccine, skin to bone depth, prior treatments, symptom duration, source of pain and outcomes.

Patient No.	Age, yr	Sex	Vaccine	Side	Skin to Bone (cm)	Prior Treatment	Symptoms Duration (months)*	Source of Pain, Findings	Location of Bone Lesion**	QDASH Scores					
										Preop	Postoperative Week				
											2	4	12	24	52
1	65	F	Pneumococcal	Right	1.8	CS, PT	42	IS, CI, B	115°	61	11	0	0	0	0
2	69	F	Influenza	Left	2.3	PRP, PT	13	TM, CI, B	145°	52	9	0	2	0	NA
3	69	F	Shingles	Left	1.3	PRP, PT	8	IS, CI, B, T	100°	89	27	2	0	0	0
4	59	M	Influenza	Left	2.2	CS, PT	12	IS, CI, B, T	115°	57	7	5	2	2	0
5	33	F	Influenza	Left	1.6	PT, CS, AS	23	TM, CI, B	105°	66	2	0	0	0	0

F, female; M, male; CS, corticosteroid; PT, physical therapy; PRP, platelet-rich plasma; AS, arthroscopic surgery; IS, infraspinatus, TM, teres minor; CI, cortical irregularities; B, bone lesion/edema; T, tendinosis/mucoid degeneration; QDASH, Quick Disabilities of the Arm, Shoulder, and Hand; NA, not available.

* No patients reported shoulder pain prior to their vaccinations and all reported its onset immediately afterwards.

** Location of bone lesion relative to the intertubercular sulcus of the humerus in degrees on axial MRI.

had been an accumulation of microbubbles throughout the targeted tissue. The total amount of circulating fluid (normal saline) used in each case was 50–100 ml. The device was then withdrawn, excess fluid was allowed to drain from the wound, and a closure strip and dry sterile dressing were applied. The duration of the procedure, including setting up and preoperative scanning before skin preparation and draping, was typically on the order of 1 h. Patients were advised to rest their arm that day and resume activities as tolerated the next day.

2.4. Statistical analysis

Statistical analysis was performed using GraphPad Prism, version 8.4.3, software (GraphPad Software Inc, La Jolla, CA). The dependent input factor was the QDASH score, while the independent was the vaccination. The data set contained a missing value at 1 year because of a random event, making it unsuitable for analysis via repeated measures analysis of variance. Therefore, a mixed model implemented in GraphPad Prism was applied, which uses a compound symmetry covariance matrix and is fit using restricted maximum likelihood [27]. Sphericity was not assumed (Greenhouse-Geisser correction). All postoperative time points were compared with the preoperative QDASH score and with each other (e.g., week 2 versus 1 year) with Tukey's post-hoc test with 95% confidence intervals. The results of this test can be interpreted in the same manner as a repeated measure 1-way analysis of variance with Tukey's post-hoc test.

2.5. Case series

2.5.1. Patient 1

In February 2016, a 65-year-old woman with no history of shoulder pain received a pneumococcal vaccine to her right shoulder and experienced immediate severe pain. One week later she also reported mild weakness in flexion of the middle, ring, and little fingers of the right hand. The cause of the weakness, in light of her normal electrodiagnostic tests, was most likely from pain-related inhibition. Her shoulder pain improved over a period of months from 7–8 to 5–6 on a 10-point scale (with 0 indicating no pain and 10 indicating the worst possible pain) for the next 2 years.

In January 2018, because of persistent shoulder pain and finger flexion weakness, she was referred to us for neuromuscular and electrodiagnostic consultation, which showed no evidence of radiculopathy, plexopathy or other neuropathy. By September 2018, her finger flexion weakness had resolved, but her shoulder pain persisted. Shoulder MRI showed a bone lesion of the posterior humerus at the insertion of the infraspinatus tendon, a partial-thickness tear of the supraspinatus tendon, mild subdeltoid bursitis and partial-to full-thickness cartilage loss in the glenoid fossa.

In October 2018, she experienced a severe exacerbation of anterolateral shoulder pain, which improved for several months after ultrasound-guided injections to the subacromial bursa and glenohumeral joint, each with 2 ml of 0.5% ropivacaine and 20 mg of triamcinolone

acetone (40 mg/ml, Bristol-Myers Squibb, Princeton, NJ). In March 2019, she returned with ongoing pain and impairment of shoulder movement and sleep. She received an injection of 2 ml of 0.5% ropivacaine plus 40 mg of triamcinolone acetone into the glenohumeral joint, which completely relieved her symptoms for 2.5 months. Her temporary positive response to long-acting corticosteroids is consistent with their duration of effect and known immune-suppressant properties.

In June 2019, her right shoulder abduction and overhead activities were limited because of pain. On ultrasound examination, there was tenderness to sonopalpation at the infraspinatus tendon insertion, where a 1-mm protuberance of the cortex was noted. The relevance of this protuberance is unknown, but it was at the same location as the lesion noted on MRI, and was confirmed as the source of her pain after an injection of 0.5 ml of 4% lidocaine temporarily eliminated her pain and improved her range of motion.

In August 2019, after informing our patient of the rationale for the procedure and that it had been used for tendinopathies but not this specific indication, we performed ultrasound-guided ultrasonic aspiration and debridement of the infraspinatus tendon and underlying bone at the previously identified location, with 2 min and 15 s of activation at the medium and high settings (Appendix B). The tendon was unremarkable in appearance but felt abnormally soft. Several cubic millimeters of bone were removed at the location of the cortical protuberance. After the procedure, she experienced some improvement of her shoulder pain within 48 h. Within 2 weeks, her pain had resolved and her range of motion was normal. Her QDASH score improved from 61 points preoperatively to 11 points at 2 weeks postoperatively and 0 points at 4, 12, and 24 weeks and at 1 year postoperatively.

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2.5.2. Patient 2

In September 2018, a 69-year-old woman with a history of chronic disease and no history of left shoulder pain received an influenza vaccination to her left shoulder. Within several hours, she experienced swelling and a sensation of “deep bony pain” radiating from the back of her left shoulder to her wrist. Thereafter, she had left shoulder weakness and pain at 6–9 on a 10-point scale, which was worse with shoulder flexion and abduction. In November 2018, MRI of the left arm from the shoulder to the elbow showed a lower posterior labral tear, mild posterior humeral subluxation and edema of the posterior humeral head at the insertion of the teres minor.

In February 2019, she was referred to our clinic for electrodiagnostic evaluation of ongoing weakness and bilateral arm pain radiating to the shoulder blades. Nerve conduction studies showed chronic median neuropathy at the left wrist consistent with carpal tunnel syndrome. Ultrasonography showed a small left supraspinatus tendon articular-sided tear and a common elbow extensor tendinosis, for which she was treated with leukocyte-poor, platelet-rich plasma (LP-PRP) injections. After 1 month, her left shoulder and elbow pain were improving.

In October 2019, she presented again with left shoulder pain, particularly in abduction and external rotation. Ultrasonography examination revealed cortical abnormalities and sonopalpation elicited focal tenderness at the teres minor tendon insertion. A local anesthetic injection at this location provided substantial improvement of her pain. Ultrasonic aspiration and debridement of the distal teres minor tendon was performed, with 1 min and 35 s of activation at the medium setting. Her QDASH score improved from 52 points preoperatively to 9 points at 2 weeks postoperatively, 0 points at 4 weeks, 2 points at 12 weeks, and 0 points at 24 weeks postoperatively. She was able to perform all activities of daily living without pain. At 1-year follow-up, we were informed that she had died of unrelated causes.

2.5.3. Patient 3

In January 2019, a 69-year-old woman with no history of shoulder pain received the second in a series of 2 shingles vaccinations to her left

shoulder. She experienced immediate left shoulder pain, which radiated down her arm and into her fingertips. She described the pain as a burning with “pins and needles” sensations, rated at 7 on a 10-point scale. Her symptoms were aggravated by driving a motor vehicle and lying down. She was unable to do yoga, dance, or hike without pain. In July 2019, her family physician ordered an MRI of the cervical spine, which showed spondylosis and mild multilevel foraminal stenosis.

In August 2019, she came self-referred to our clinic for “neck pain,” which radiated down the left arm and into the hand. The pain had started immediately after the vaccination and had continued to get worse. Her left shoulder abduction was limited to 80° and there was resistance to passive external rotation. Her ipsilateral neck rotation was limited to 30° and her sensation to light touch was slightly reduced over the lateral arm and forearm. We provided a diagnostic anesthetic injection to her subacromial bursa, which relieved her pain slightly, and then to her glenohumeral joint, which relieved her pain substantially. We diagnosed her with mild adhesive capsulitis and injected her glenohumeral joint with LP-PRP the following day [28].

By September 2019, some of the radiating pain had improved, but she continued to have pain at night and with shoulder abduction, flexion, and external rotation. She had severe pain when reaching for the back of her neck (severity, 8/10) or using her arm for pushing (severity, 9/10). There was loss of the normal echotexture on ultrasonography and tenderness to sonopalpation of the distal infraspinatus tendon. An ultrasound-guided anesthetic injection with 1 ml of 4% lidocaine at this location resulted in complete temporary relief of shoulder pain and restoration of motion. This anesthetic injection was repeated the following day, confirming the result.

In October 2019, shoulder MRI showed signal change in the deep fibers of the infraspinatus tendon with microcystic changes in the adjacent posterior humerus (Figure 3A,B), mild supraspinatus tendinosis and an interstitial tear. A week later, we performed ultrasonic aspiration and debridement of the distal infraspinatus tendon at its insertion with 2 min and 30 s of activation at the medium setting (Figure 3C,D), followed by 1 min of activation at the high setting to debride an adjacent bony lesion. At 10 days following her procedure, her pain and function had improved substantially. She had mild residual shoulder impingement for which, based on her preference to avoid corticosteroids, we provided her with an ultrasound-guided injection of 4 ml of LP-PRP to the subacromial bursa. At 14 days following her procedure, her QDASH score had improved from 89 to 27 points, then 2 points at 4 weeks, and 0 points at 12 and 24 weeks and 1 year. She was able to resume yoga, dance, and hike without pain.

The complete resolution of her shoulder pain and disability was not attributable to treatment of her adhesive capsulitis with the first LP-PRP injection 2 months prior to the ultrasonic procedure. This is evidenced by the fact that prior to her ultrasonic procedure a low volume (1.0 ml) diagnostic anesthetic injection to the infraspinatus tendon insertion completely resolved her shoulder pain with the pain score improving from 8/10 to 0/10. If her pain had been attributable to adhesive capsulitis, it would not have improved with an anesthetic injection at this location. Also, the location of the anesthetic injection was not contiguous with the joint space, so LP-PRP injected into the joint space could not have reached it.

2.5.4. Patient 4

In October 2018, a 59-year-old man with no history of shoulder pain received an influenza vaccination to the left shoulder. He immediately experienced sharp pain at the injection site. The pain worsened during the next 5 weeks and eventually involved the entire shoulder, upper back, and left arm. Before the vaccination, he was able to perform 50 push-ups a day and bench press 114 kg (250 lbs). He underwent physical therapy, consulted with an orthopedic surgeon and received 40 mg of triamcinolone acetone divided between his subacromial space and glenohumeral joint, which improved his pain from 7 to 3–4 on a 10-point scale for 1 month.

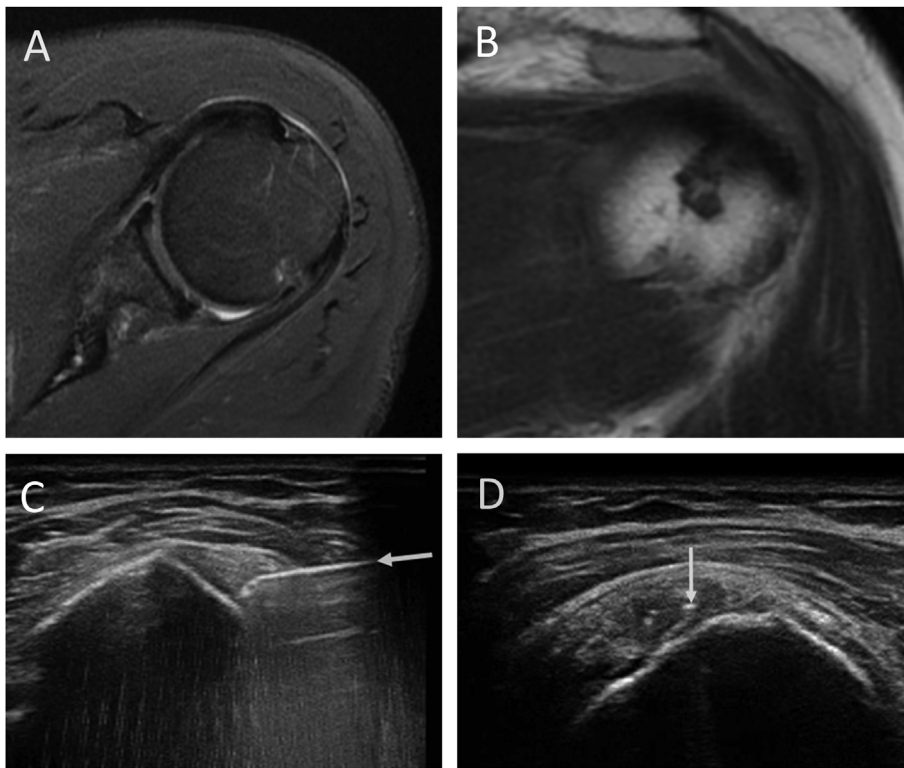


Figure 3. Patient 3. (A) Axial T2-weighted fat-suppressed and (B) coronal proton density-weighted MR images show a bone lesion in the posterior humerus adjacent to the distal infraspinatus tendon, which has a signal change in its deep fibers. The lesion is located at 100° relative to the intertubercular sulcus. (C) Long-axis, and (D) short-axis 12 MHz intraoperative ultrasound views of the ultrasonic aspiration and debridement cannula (arrows) within the infraspinatus tendon, which exhibits an abnormal hypo-echoic (dark) echotexture next to the cannula in (D).

In February 2019, because of ongoing pain and disability he underwent magnetic resonance (MR) arthrography, which showed severe glenohumeral joint osteoarthritis (Figure 4A), edema in the deep fibers of the infraspinatus tendon, an adjacent bone lesion or cyst (Figure 4B, D), a split tear of the long head of his biceps tendon, a degenerative labral tear,

mild partial-thickness supraspinatus and subscapularis tendon tears, and mild chronic reactive synovial hypertrophy.

In May 2019, he was referred to our clinic for ongoing shoulder pain and dysfunction and the recent onset of numbness in the left arm. We injected his glenohumeral joint with 5 ml of 0.5% ropivacaine and 20 mg

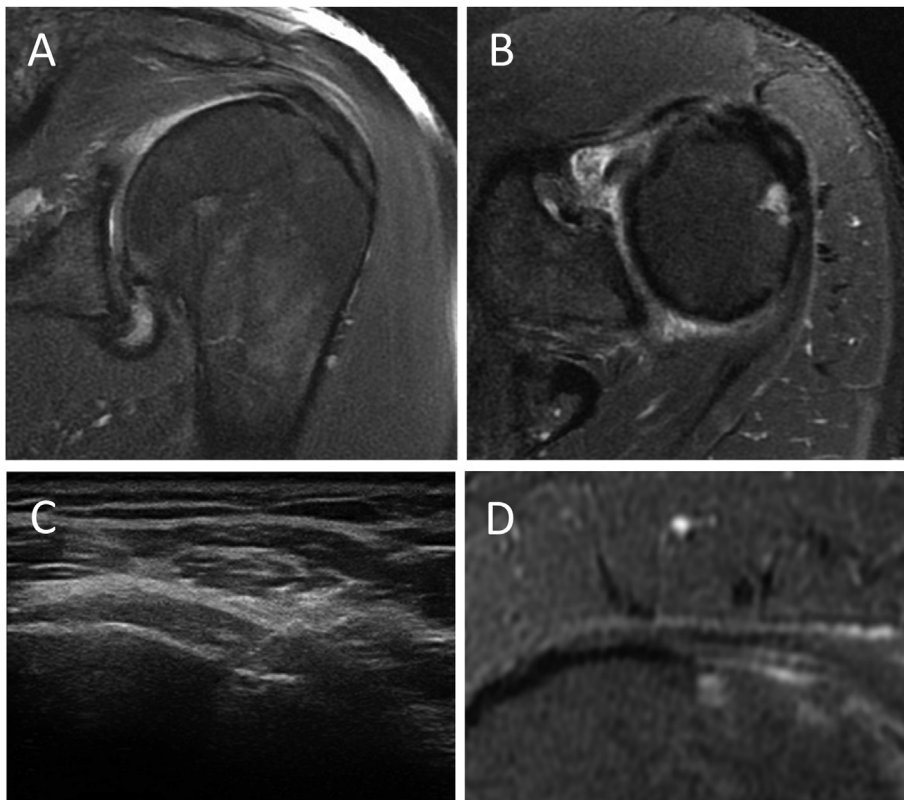


Figure 4. Patient 4. (A) Coronal T2-weighted fat-suppressed MR arthrogram showing moderate osteoarthritis with full-thickness cartilage loss of the superomedial aspect of the humeral head and upper glenoid unrelated to the vaccination. (B) Axial STIR MR arthrogram showing edema in the infraspinatus tendon and an adjacent bone lesion. (C) Long-axis 12 MHz intraoperative ultrasound image showing the infraspinatus tendon and the ultrasonic cannula (diagonal line) next to the bone lesion. (D) Axial STIR MR arthrogram, slice immediately adjacent to image in (B), rotated and magnified to correspond to ultrasound image in (C).

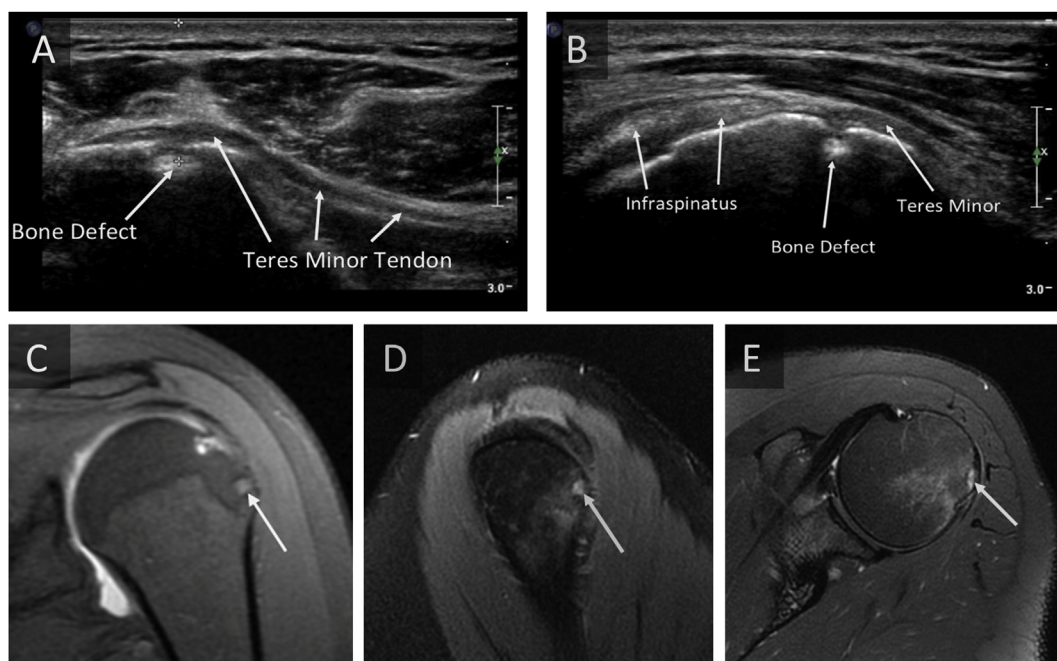


Figure 5. Patient 5. 17.5 MHz ultrasound images showing (A) long-axis and (B) short-axis views of the distal teres minor tendon and an underlying bone defect or lesion. (C) Coronal T1-weighted fat-suppressed MR arthrogram showing the bone defect or lesion (arrow). An incidental intraosseous cyst is noted at the posterior superolateral humeral head margin. Sagittal (D) and axial (E) fat-suppressed proton density-weighted MRI showing the bone defect or lesion (arrow) with mild edema in the adjacent bone marrow and teres minor tendon. The distance between the skin and the bone defect is 1.6 cm, as measured between the "+" marks in (A).

of triamcinolone acetonide (40 mg/ml), providing substantial improvements in left shoulder pain and range of motion for 1 month.

In July 2019, he reported that our injection had allowed him to take a month-long trip, but then the pain returned to a level of 7 on a 10-point scale. We performed ultrasonography and noted focal tenderness at the infraspinatus tendon insertion, where there was a cortical bone irregularity at the site of the lesion seen on MR arthrography (Figure 4B, D). We injected this location with 1 ml of lidocaine 4%, resulting in 50% temporary improvement of his shoulder pain.

In October 2019, we performed ultrasonic aspiration and debridement of approximately 1 cubic centimeter of the distal infraspinatus tendon, its insertion and the adjacent bone lesion with 4 min of activation at the medium and high settings (Figure 4C). On postoperative day 4, he exercised on an elliptical machine without pain. His QDASH score improved from 57 points preoperatively to 7 points at 2 weeks postoperatively, 5 points at 4 weeks, and 2 points at 12 weeks postoperatively.

In January 2020 he was doing 30 push-ups several days per week. While performing a resistance exercise to the end range of motion during physical therapy, he experienced a "give-way" sensation and "locking" of his shoulder, followed by severe pain. He described this new pain as anterior and deep, different from his original posterior shoulder and arm pain which remained resolved since his procedure. Repeat MRI showed mild to moderate subacromial-subdeltoid bursitis, but was otherwise unchanged.

We diagnosed his new pain as caused by his glenohumeral joint osteoarthritis. In March 2020, to alleviate this pain we injected 6.5 ml of bone marrow aspirate concentrate with a total nucleated cell count of 1.4 billion into the glenohumeral joint [29]. Six weeks later, his pain and range of motion had improved, and he was doing 20 push-ups several days per week. At 24 weeks after aspiration and debridement his QDASH score was 2 points.

At 34 weeks, his anterior shoulder pain returned suddenly while playing golf, raising his QDASH score to 25. His occupational medicine physician injected his glenohumeral joint with 80 mg of methylprednisolone (80 mg/ml), reducing his QDASH to 9 for 2 weeks. At 40 weeks

his QDASH score was 40, and at 1 year was 32, still better than 57 prior to the ultrasonic procedure. However, because of ongoing anterior shoulder pain and disability, he asked to be referred for a total shoulder arthroplasty. His original posterior shoulder and arm pain which had resolved by week 4 after his ultrasonic procedure and was related to his infraspinatus tendon remained resolved.

2.5.5. Patient 5

In November 2017, a 33-year-old woman with no history of shoulder pain received an influenza vaccine to her left shoulder. She experienced substantial pain immediately after the vaccination and awoke the next day with constant dull pain and soreness in her left shoulder and arm. During the next several days and weeks her shoulder pain increased to 10/10. The pain radiated down the arm and she experienced prickling and tingling sensations and numbness in the hand. She underwent physical therapy, took diclofenac and oral steroids with minimal to no improvement.

In April 2018, because of ongoing pain she underwent MRI, showing an intraosseous cyst with mild marrow edema at the posterior aspect of the greater tuberosity. She saw an orthopedic surgeon in her community who noted tenderness of her biceps tendon, glenohumeral joint and subacromial bursa, and injected her biceps tendon sheath with betamethasone 6 mg and lidocaine 1%, providing minimal relief for 2 days.

In August 2018, because of ongoing shoulder pain and dysfunction her orthopedic surgeon performed arthroscopy, finding mild synovitis at the posterior labrum and thickening of the posterior capsule, which was debrided. By November 2018, she had minimal improvement with her worst pain at 4/10 and best at 2/10, and this while taking hydrocodone 7.5 mg-acetaminophen 325 mg every 4 h, ibuprofen 800 mg every 8 h and applying lidocaine-prilocaine 2.5%–2.5% cream. Her shoulder flexion and abduction were 150°, and external rotation was 60°.

In January 2019, she sought consultation at an academic orthopedic shoulder center, where she was diagnosed with mild tendonitis and adhesive capsulitis. The treating shoulder fellow concluded that her degree of disability was disproportionate to the findings. By July 2019, she continued to have considerable pain and disability. MR arthrogram

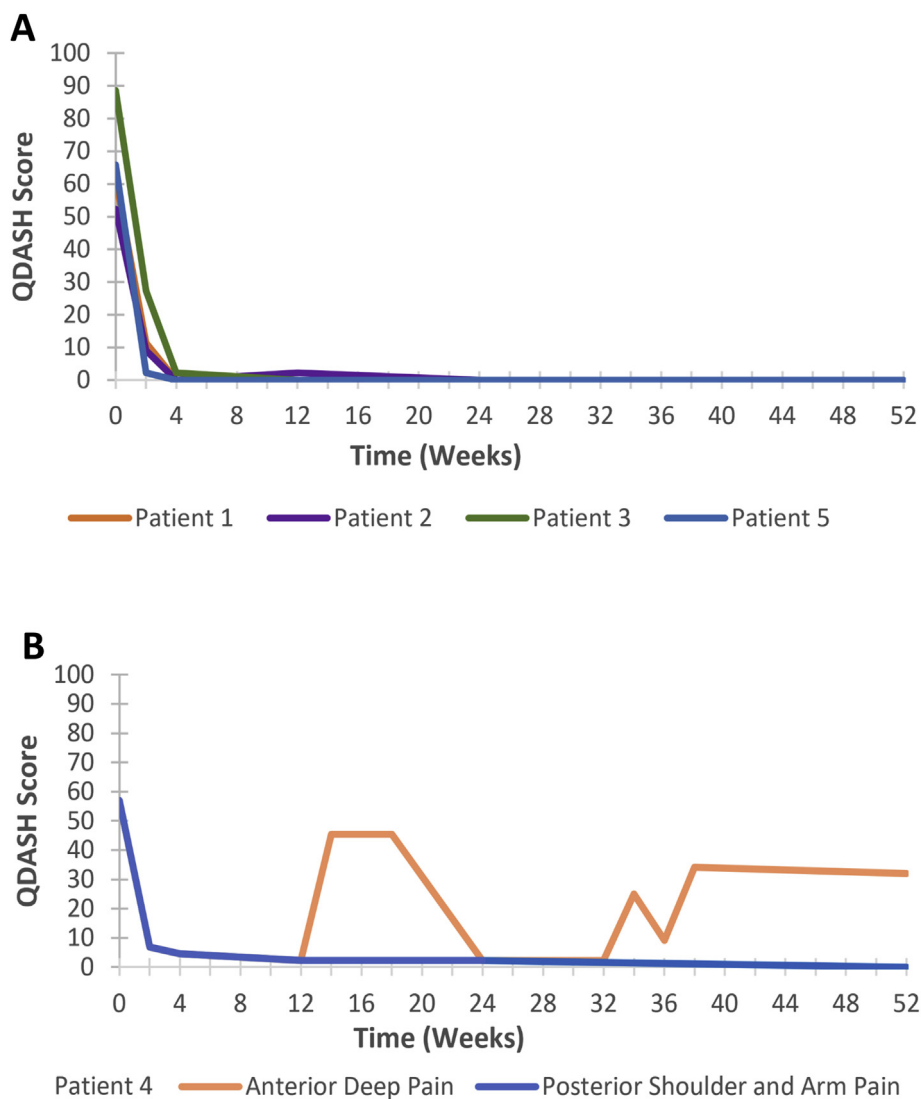


Figure 6. Post-operative resolution of shoulder pain and dysfunction as assessed by the Quick Disabilities of the Arm, Shoulder, and Hand (QDASH) scores in (A) Patients 1, 2, 3, and 5; and (B) Patient 4, showing resolution of his post-vaccination posterior shoulder pain (blue) and onset of his osteoarthritis-related anterior shoulder pain (orange).

suggested a superior labrum tear. Her community orthopedist performed another arthroscopy, seeing a small partial rotator cuff tear at the greater tuberosity and what he thought was an anterior labrum tear, both of which were repaired. Grade-I chondromalacia in the glenoid was also noted.

In October 2019, she came self-referred to our clinic with pain worse since her last surgery. She had pain and difficulty abducting her arm 70°–80° and severe pain when reaching across her chest or transitioning from internal to external rotation. Ultrasonography revealed a 5-mm cortical bone lesion under the teres minor tendon insertion, where she was focally tender to sonopalpation (Figure 5A,B). Our review of her MRI revealed this lesion, which had not been mentioned previously (Figure 5C,E). We injected 0.75 ml of a 50/50 mix of 4% lidocaine and ropivacaine 0.5% at this location and noted that the tendon felt abnormally soft. Afterwards, her shoulder pain decreased from 4 to 2 on a 10-point scale, and her arm pain resolved completely.

The next day, we performed ultrasonic aspiration and debridement using the medium and high settings with 1.5 min of activation for the teres minor and 2 min for the adjacent bony lesion. She noticed improvement in pain and range of motion in the recovery room. On the second night after the procedure, she slept through the night without pain, including on the affected side, for the first time in 2 years. She

required no medications. Her QDASH score improved from 66 points preoperatively to 2 points at 2 weeks postoperatively and 0 points at 4, 12, and 24 weeks and at 1 year postoperatively. At 1 year she had slight tightness when fully flexing her shoulder, possibly related to her labrum surgery. She returned to playing basketball and lifting weights without pain.

3. Results

The distal infraspinatus and teres minor tendons, their insertions and or the adjacent bone were found to be the source of shoulder pain in all 5 patients. Ultrasonography revealed cortical bone irregularities, sonopalpation elicited focal tenderness, and local anesthetic injections resolved pain at these locations in all 5 patients. MRI showed tendinopathy, bone lesions or edema at these locations in all 5 patients. If on axial MRI the cross-section of the humerus is depicted as a circle, the point at which the bone lesions or edema reached the surface of the humerus was at 115°, 145°, 100°, 115°, and 105° relative to the inter-tubercular sulcus.

After ultrasonic aspiration and debridement, all of our patients experienced rapid and near-complete resolution of pain and function, with the mean QDASH improving from 65 points to 11 points at 2 weeks



Figure 7. Photograph of a patient showing the location (x) of the distal teres minor tendon under the upper third of the deltoid muscle. In her case, the distance from the skin to the teres minor tendon is 0.7 cm as determined by ultrasound. The infraspinatus tendon is located approximately 1 cm superior.

($P = 0.001$), and to 1 point at 4 weeks ($P = 0.003$). Improvements in pain and function were stable for at least 1 year in 3 patients (Figure 6A), 24 weeks in 1 patient who later died of unrelated causes, and 1 year for the post-vaccination component of pain in 1 patient (Figure 6B), who developed new onset symptoms related to his previously asymptomatic moderate to severe osteoarthritis ($P = 0.013$).

4. Discussion

We aimed to develop a consistent and effective method of diagnosing and treating patients with chronic shoulder pain after a vaccination. In patients with chronic pain, imaging studies often do not reveal the source of pain. In one case of shoulder pain after an influenza injection, MRI showed edema of the distal teres minor tendon and adjacent bone at 2 months, but at 3 years the edema had resolved while the pain remained (Figure 1A) [10]. In another case, MRI showed progressive enlargement of bony lesions over 8 months, which upon surgical debridement resulted in resolution of pain (Figure 1B) [14].

Imaging studies also often reveal incidental findings, such as a normal variant sublabral recess, partial-thickness rotator cuff tears and mild osteoarthritis. Sonopalpation and diagnostic anesthetic injections help to differentiate these findings from the actual source of pain. In the spine, anesthetic injections are often used to diagnose the source of pain [30, 31]. Placebo effects or malingering can be assessed using blinded injections or anesthetics with different durations of effect [30, 31].

Ultrasonic aspiration was originally developed to break up and aspirate cataracts, a procedure known as phacoemulsification [32], and more recently has been widely used throughout the United States with over 130,000 procedures performed as an alternative to open surgery for degenerative tendinopathies [18, 19, 20, 21, 33]. A cannula with a needle inside vibrating at 28 kHz is used to disrupt and aspirate diseased soft tissue and bone. Circulating fluid passes between the cannula and the needle to reach its tip before being aspirated through its lumen.

Our cases demonstrate involvement of the distal teres minor and infraspinatus tendons, capsules and underlying bone, where cortical irregularities, lesions and edema were noted. These structures are at risk if

a vaccination is provided at the upper third of the deltoid muscle (Figure 7). The strength of our series is that it represents males and females, younger and older patients, some with osteoarthritis and partial rotator cuff tears, all of whom had undergone multiple treatments without significant or lasting improvement for over a year and a half on average prior to undergoing the aspiration and debridement procedures.

In addition to the primary symptom of shoulder pain, each of our patients described some transient pain in the arm, numbness sensations or weakness. Symptoms such as these have been described previously in patients with chronic shoulder pain, resolving temporarily with anesthetic injections and permanently with definitive treatment of their shoulder pathology [34, 35, 36, 37]. This was also the case with our patients and would not have occurred if radiculopathy or another neurologic condition had been the cause of their symptoms.

All 5 of our patients had abnormalities at the posterior or inferior facet of the greater tuberosity of the humerus, 4 of which were located at 100–115° from the intertubercular sulcus, which is just under the middle of the upper third of the deltoid muscle when a person is seated with their arm in internal rotation. The outlier of 145° was in an obese patient, whose abdomen most likely pushed her elbows away from her body requiring greater internal rotation of her arms to place her hands in her lap when getting vaccinated. Among 238 consecutive patients at an academic medical center with rotator cuff diagnoses at surgery, 56.7% exhibited bone lesions at the posterior facet and 22.7% at the anterior facet on their pre-operative MRI [38], a distribution roughly corresponding to the relative size of the facets [39]. This is higher than the prevalence of bone lesions in the normal population, which is 13–27% based on radiographs [38].

The success of our procedures may be attributable to the resolution of tendinopathy, antigen-mediated pain or immune-mediated inflammation. The mechanism may involve debridement of degenerated and inflamed tissue, stimulation of a healing response, or washing away of residual vaccine, analogous to equilibrium partitioning of a contaminant from a solid surface binding back into liquid solution in hydrogeology [40].

It should be noted that 3 of our patients had complete and 2 partial temporary resolution of pain after anesthetic injections, but all had essentially complete resolution of pain after their procedures. With regard to the latter 2 patients, this may have been because some of their pain could have been from the underlying bone, which may not have been completely anesthetized at the time of the diagnostic injection, or because inflammation from the primary pain source was causing more widespread pain and dysfunction.

Since treating the 5 patients described in this series, we have seen and treated an additional 15 patients, 12 of which had greater than 50% temporary relief of symptoms with local anesthetic injections to the infraspinatus or teres minor tendons and went on to have similar outcomes. Three of these 15 patients did not have more than 50% improvement of their pain with diagnostic anesthetic injections and their outcomes were not as successful.

In theory, the supraspinatus tendon could also be the source of pain and likely would respond similarly to aspiration and debridement. As for the bursa itself being the primary source of pain, the chances of vaccine being injected purely into the bursa are low because it is normally very thin, on the order of 1 mm [41]. There is a much greater chance of the vaccination needle passing all the way through the deltoid, bursa, rotator cuff and capsule before encountering the bone of the humerus. Hypothetically, vaccine injected at that location would mostly be deposited near the tip of the needle but could also spread in multiple directions within the criss-crossing fibers of the capsule [42], medially or laterally along the fibers of the infraspinatus or teres minor tendons, and from there or back up along the needle into the bursa. Reports of glenohumeral joint effusions raise the possibility that vaccine can be injected directly into the joint or spread into it [7, 43].

The primary limitation of our study, as with all case series, is that it lacks a control group. However, the patients served as their own controls

because they had tried multiple treatments for 20 months on average without success. Before considering a randomized controlled trial, our goal was to determine whether our treatment was at all successful and this was achieved. An additional limitation is that there is currently no method of determining whether vaccine was present in the aspirated tissue. As such we cannot prove that residual vaccine or a reaction to it was the cause of pain.

At this time, we do not know whether both the tendons and bone need to be treated and when, how extensive the treatment needs to be, and whether the treatment would have been as effective in patients with larger bony lesions. Also, we do not know whether our procedures would have been as effective in more recently afflicted patients. One of our patients (Case 3) received LP-PRP 1 month before and 10 days after her procedure, potentially confounding her outcomes. If her case were to be removed from the series, the outcomes of the remaining 4 would still be significant at all time points ($P < 0.01$).

The physician performing the procedures had more than 17 years of experience with ultrasonography and ultrasound-guided interventions and used high-end equipment. The results cannot be generalized to procedures performed by someone with less experience, using different equipment and not spending adequate time to do a thorough diagnostic assessment and procedure. The efficacy of our procedures cannot be compared to other treatments because recognition that the infraspinatus and teres minor tendons are a common source of chronic shoulder pain after a vaccination is new as of this article. Simpler and less costly treatments, such as needle tenotomy and lavage, might also be effective.

5. Conclusion

The distal infraspinatus and teres minor tendons, their insertions and or the adjacent bone were the source of pain in a consecutive series of 5 patients with chronic shoulder pain after a vaccination. Ultrasound-guided ultrasonic aspiration and debridement was effective at resolving pain and disability in all 5 patients. Outcomes remained stable at 1 year in 3 patients, at 24 weeks in 1 patient who later died of unrelated causes, and at 1 year for the component of pain and dysfunction that started after the vaccination in 1 patient ($P = 0.013$). The results are consistent with the hypothesis that vaccination-related shoulder dysfunction is caused by the effects of unintentional vaccine injection into the rotator cuff with spread to adjacent structures. At a time of increased vaccinations worldwide, the results are promising and should be confirmed in a larger study and randomized controlled trial in the future.

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