Heated Lidocaine-Tetracaine Patch for Management of Shoulder Impingement Syndrome

Richard Radnovich, DO

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Address

correspondence to Richard Radnovich, DO, Injury Care Medical Center, 4850 N Rosepoint Way, Suite 100, Boise, ID 83713-5262

E-mail: dr.radnovich @injurycaremedical.com

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Shoulder impingement syndrome (SIS), a chronic shoulder pain condition, often stems from repetitive overhead activities. In the current report, the author presents 2 cases of SIS. In the first, a woman with a history of SIS found that physical therapy and subacromial steroid injections, while effective, were problematic for long-term use. Previous use in the author's practice demonstrated convenient shoulder pain relief using the heated lidocaine 70 mg-tetracaine 70 mg topical patch. She initially used the heated lidocaine-tetracaine patch twice daily and tapered over 4 weeks to as-needed use for successful pain control. In the other case, a female adolescent athlete with a history of SIS tried, on the recommendation of the author, using the heated transdermal patch instead of steroid injections. Her pain was successfully controlled during activity and at rest with 12 hours-on/12 hours-off patch application. The heated lidocaine-tetracaine topical patch may be an early conservative treatment for patients with acute pain from SIS and warrants examination in controlled studies

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houlder impingement syndrome (SIS) is one of the most common intrinsic causes of shoulder pain and disability. Although SIS is considered a chronic condition—most often in athletes whose sports involve throwing—it has also been observed in nonathletes, particularly in those whose activities involve repetitive overhead motion. The American Academy of Orthopaedic Surgeons describes SIS as pain and irritation resulting from the acromion rubbing or impinging on the tendon and bursa of the rotator cuff (*Figure 1*). Pain caused by SIS is due to functional impairment of the bursa, the long head of the biceps, and the rotator cuff.

In adults younger than 65 years, prevalence of shoulder pain ranges from 1.8% to 12.5%, whereas in adults 65 years or older, the range is 13.1% to 13.4%.56 Current treatment options include nonsteroidal antiinflammatory drugs (NSAIDs), corticosteroid injections, oral corticosteroids, surgery, and physical therapy.^{5,7} Additional therapies under investigation for SIS not included in the guidelines are osteopathic manipulative treatment, prolotherapy, and platelet-rich plasma injections in conjunction with surgical treatment.8-11 The best treatment for patients with this condition is still to be determined, as there are many stages of rotator cuff problems. The American Academy of Orthopaedic Surgeons has some recommendations for the management of rotator cuff problems (Figure 2), but most organizations do not have consensus recommendations; therefore, other therapies to treat patients with this disease state are needed.7 In the present article, I report 2 cases of SIS successfully managed with a heat-activated topical patch.

Report of Cases

Patient 1

A.W., a woman whose job requires repetitive overhead motion, presented to my office with right shoulder pain. She was otherwise healthy, with a history of multilevel cervical fusion for spondylosis, occasional neck pain, and lumbar spondylosis managed with occasional facet block injections. Furthermore, she had a history of rotator cuff impingement on the left side, her nondominant side. A.W. had courses of physical therapy and subacromial injections given episodically by other providers, with the most recent injection being 6 months before presentation and the most recent course of physical therapy being 1 month before. Previous physical therapy course duration was 8 sessions over 4 to 5 weeks. Physical therapy and subacromial anesthetic and corticosteroid injections provided temporary relief of pain for a few days to a few weeks. After these treatment modalities failed to provide long-term pain relief, A.W.'s left shoulder was surgically treated with arthroscopic subacromial decompression and débridement by another physician 12 weeks before presentation.

At presentation, A.W. had pain in the anterolateral shoulder region at rest, which increased as she reached up and back. Several weeks earlier, she reported to another physician the insidious onset of right shoulder pain when she was lying on her right side. The pain was not seemingly caused by injury or change in activity. Physical examination revealed pain with terminal flexion of the right shoulder (positive for impingement on the Neer test) and pain with internal rotation. There was no instability in the right shoulder or weakness in the upper extremities. Palpatory examination revealed tenderness in the anterior shoulder region, at the attachment of the supraspinatus and the infraspinatus tendons. At this point, no imaging of the right shoulder had been performed. The other results of the physical examination were unremarkable.

Her condition was diagnosed as rotator cuff impingement syndrome on the basis of clinical presentation and physical examination findings. Her occupation, however, limited the means by which she could manage the pain. A.W. was subject to the considerable medication restrictions from a federal regulatory agency. For example, she was not allowed to use any medications that cause sedation, such as hydrocodone and tramadol. Her work regulations did permit evaluations of medications on a case-by-case basis. Although she was not working at the time of presentation, A.W. nonetheless wanted to avoid certain oral medications to be certain of her ability to return to work. Also, she considered physical therapy too time consuming and steroid injections as impractical for long-term or repeated use.

A.W. was given the heated lidocaine 70 mg-tetracaine 70 mg topical patch (Synera, ZARS Pharma, Inc, Salt Lake City, Utah) initially twice per day, applied to the most palpably painful area on her shoulder for 3 to 4 hours per week and then tapered to as-needed use during the course of 4 weeks. She used 6 patches during the as-needed period. After treatment with the heated lidocaine-tetracaine patch, her pain resolved completely, and she was able to resume normal activities. She maintained normal function, continued her home exercise regimen which was aimed at improving shoulder function—and had her pain well controlled during this time. She was seen in my office at regular intervals for 15 months after the use of the heated lidocaine-tetracaine patch for treatment unrelated to SIS. She moved out of the area about 1 year ago and was lost to follow-up.

Patient 2

C.L., an adolescent girl, presented to my office with an 18-month history of rotator cuff impingement. She played volleyball on an elite-level year-round high school team and hoped for a college scholarship play-

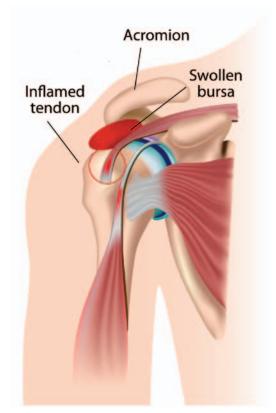


Figure 1.

Musculoskeletal view of shoulder impingement syndrome. Pain or irritation occurs when the acromion rubs against or impinges the tendon and bursa of the rotator cuff

ing the sport. She was given a diagnosis of rotator cuff impingement by multiple health care providers.

C.L. presented to her previous physician with a complaint of pain in the anterior part of her right shoulder. The pain was worse during activity, particularly when raising the right arm above shoulder level, lifting, and reaching back. Although pain symptoms had generally improved with rest and application of ice packs, they did not resolve. No distinct injury or event caused the symptoms, which emerged gradually. The patient underwent physical therapy and was given NSAIDs—a trial of ibuprofen, 400 mg, every 6 hours followed by a trial of etolodac, 400 mg, twice daily—which temporarily reduced symptoms but after several months did not resolve the symptoms. She had limited her participation in volleyball by decreasing her intensity of play and decreasing her practice time because of her ongoing symptoms.

On presentation to my office, the patient rated her pain as mild to moderate at rest and severe with overhead activity. She had been referred to me for subacromial corticosteroid injections because district volleyball finals were approaching.

On examination, the patient appeared healthy with tenderness near the attachments of the supraspinatus and infraspinatus tendons on the injured (ie, right) side. She also had positive results for pain on the Neer test and the Hawkins test. The results of the remaining orthopedic and neurologic examinations were unremarkable.

Rotator cuff impingement syndrome diagnosis was confirmed on the basis of her clinical presentation and physical examination findings. Diagnostic imaging tests were not performed; reasons cited included insufficient time to review the results before the volleyball competition and the imaging results would not have changed C.L.'s ability to play, as she had been playing with the injury for months (ie, at a decreased intensity and with limited practice time) without it worsening. I discussed other treatment options with the patient. Even though the patient had heard steroids were damaging to joints, she expressed an interest in injections for the reported potentially rapid relief. I was reluctant to inject the young athlete's shoulder before the anatomic injury was confirmed. In addition, I was concerned that an injection with steroid and anesthetic could limit protective proprioception and potentially worsen the underlying disease. I elected to prescribe the heated lidocaine-tetracaine patch.

Although C.L. was initially disappointed about not receiving an injection, she agreed to try the heated lidocaine-tetracaine patch. C.L. administered the heated lidocaine-tetracaine patch as directed, applying it to the painful area at the attachment site of the supraspinatus tendon and leaving it on for 12 hours and off for 12 hours. Treatment started in late August on presentation to my office and continued for 10 days. Immediately after treatment, C.L. rated her pain as mild with activity and absent at rest. She was able to return to playing volleyball. Thereafter, the patient no longer complained

of shoulder pain or used any treatment and was able to complete the remaining 3 months of the volleyball season. However, C.L. returned to the clinic 9 months after initiation of treatment for recurrence of symptoms.

An arthrographic magnetic resonance image was obtained and confirmed impingement in the right shoulder, demonstrating supraspinatus tendinitis with no tears. C.L. was treated with oral piroxicam 20 mg/day, diclofenac sodium topical solution (Pennsaid, Nuvo Research Inc, Salt Lake City, Utah) as needed, diclofenac epolamine patch (Flector patch, IBSA Institut Biochimique SA, Lugano, Switzerland) as needed, and a strengthening exercise program. C.L. has since completed her senior year of high school, fielding multiple scholarships for college volleyball.

Comment

The pain associated with SIS is caused by compression of the rotator cuff and subacromial bursa against the acromion. ^{2,12} The subacromial space is reduced when the arm is raised (ie, abducted and externally or internally rotated), impinging the subacromial structures (rotator cuff, long head of the biceps, and bursa), which explains the association of SIS with repetitive overhead activities, such as throwing. ¹³

Patients with SIS experience pain and disability, which are the primary clinical features that treatment seeks to address. Exhaustive but conservative management is the initial approach to treatment before proceeding to surgical intervention. Nonoperative treatment typically consists of NSAIDs and physical therapy, aimed at increasing range of motion (ROM) and strengthening the rotator cuff. This approach has been shown to produce a "satisfactory response" among approximately two-thirds of patients. A retrospective study of 616 patients with SIS assessed 3-week indomethacin therapy followed by 6 weeks of physical therapy; after their shoulders became pain free, patients continued home exercise for 4 weeks. Sixty-seven percent of patients had a satisfactory

result, and 28% had no improvement and went on to have subacromial decompression.¹⁴ If pain persists despite use of NSAIDs, a therapeutic subacromial injection of lidocaine and a corticosteroid may address pain and allow the patient to continue a home-based physical therapy program. 14-16 Cummins et al 17 reported the results of 100 SIS patients treated with a nonsurgical treatment protocol consisting of subacromial cortisone injection and physical therapy, with 79% of patients not requiring surgery after a 2-year follow-up. Kuhn¹⁸ reviewed 11 randomized controlled trials of exercise and SIS and found that, although exercise had both clinically and statistically significant effects in decreasing pain and improving function, it was ineffective at improving ROM or strength. To my knowledge, no direct comparisons of SIS treatments have been reported; an ongoing study by Rhon et al,19

Nonsurgical Treatment

Exercise and nonsteroidal anti-inflammatory drugs for rotator cuff–related symptoms in the absence of full-thickness tears (moderate)

Surgical Treatment

Rotator cuff repair for chronic, symptomatic full-thickness tears (weak)

Early rotator cuff repair after acute injury (weak)

Acromioplasty not required (moderate)

Partial rotator cuff repair, débridement, or muscle transfers for patients with irreparable rotator cuff tears when surgical treatment is indicated (weak)

Tendon-to-bone healing (weak)

Use of noncrosslinked, porcine small intestine submucosal xenografts not recommended (moderate)

Postoperative Treatment

Cold therapy (consensus)

Figure 2.

American Academy of Orthopaedic Surgeons recommendations⁷ for treatment of rotator cuff problems. No recommendations for or against the use of the following interventions could be made: corticosteroid or pulsed electromagnetic field for rotator cuff–related symptoms in the absence of full-thickness tears, iontophoresis, phonophoresis, transcutaneous electrical nerve stimulation, ice, heat, massage, or activity modification for rotator cuff–related symptoms in the absence of full-thickness tears. Strength of consensus indicated in parentheses.

however, is comparing outcomes in pain and disability between patients with SIS who are receiving either manual physical therapy or subacromial corticosteroid injection.

Osteopathic physicians use a variety of methods to manage dysfunctions of the shoulder joint, such as the Spencer technique,²⁰ developed in 1916, and the Jones technique.²¹ Whereas both are used for a variety of shoulder complaints, to my knowledge neither has been systematically studied for use in patients with SIS.

It has been suggested that SIS is optimally managed by eliminating pain first—before restoring shoulder joint stability and movement patterns, increasing ROM, or enhancing strength.²² Progressive resistance training for the rotator cuff muscles has been shown to effectively reduce pain, as well as to improve function and quality of life in patients with chronic shoulder complaints, including SIS.^{5,23} Pain relief observed in 1 study²³ was attributed, in part, to the strengthening and resulting stabilization of the shoulder joint. Because effective strengthening of the rotator cuff muscles can initially aggravate symptoms and because pain relief as a consequence of strengthening typically has a slow onset, there is a need to immediately and directly address pain caused by SIS.

Substantial evidence supports the premise that pain should be addressed early in the management of chronic shoulder conditions. Fear that emerges in response to musculoskeletal pain may contribute to the development of chronic pain and disability. Fear-avoidance model of musculoskeletal pain links pain-related fear with the development of chronic pain and long-term disability, where pain is catastrophically misinterpreted by the patient, therefore giving rise to fear of pain, fear of movement, hypervigilance to body sensations, avoidance, and disuse. This behavior then perpetuates a cycle that results in disability, which lowers the patient's threshold for pain and activity tolerance, and thus reinforces the cycle.

The heated lidocaine-tetracaine patch can begin to break the fear-avoidance pattern. The controlled heat of the lidocaine-tetracaine patch enhances the delivery of the respective agents. It was approved by the US Food and Drug Administration in June 2005 "for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures."29 In my practice, the heated lidocaine-tetracaine patch has demonstrated excellent pain relief, convenient self-administration, and lack of cognitive impairment because of the little meaningful systemic exposure. The most common adverse events reported in clinical studies were erythema, blanching, and edema during or immediately after treatment in the area where the heated lidocainetetracaine patch was applied.²⁹ Localized reactions were generally mild, and no treatment-related serious adverse events have occurred in clinical studies.29 Results of a randomized, double-blind, crossover study³⁰ of healthy adults showed that the heated lidocaine-tetracaine patch provided greater depth and duration of topical anesthesia (based on pain and sensory depth evaluations and sensory and thermal stimuli testing) when compared with a placebo patch.

The understanding of how medications are absorbed transdermally has evolved considerably. Whereas topical treatments tend to exert effects primarily in subcutaneous tissues, researchers have at times observed a deeper saturation. Preclinical and small pharmacokinetic studies have shown that pharmacologically active agents that have been compounded with carriers and made into topical gels, liquids, or patches can extend into a joint space after topical application.31-35 For example, a study of 27 patients³¹ compared semitendinosus muscle/ tendon concentrations between ketoprofen topical 20 mg patch absorption at intervals up to 20 hours prior to anterior cruciate ligament reconstruction and oral 150 mg ketoprofen capsule administration 14 hours prior to reconstruction. One hour after topical application, ketoprofen was detected in the semitendinosus muscle and tendon and gradually increased to a peak concentration at 6 hours after application.³¹ There was no statistically significant difference in tissue concentration between oral and topical groups 14 hours after administration or application.³¹ The amount of medication present in the tissues varies as a result of factors such as the characteristics of the medication, vehicle, tissue being penetrated, and application time. I propose that once within the joint, the mechanism of action of the drug is the same as it would be if the drug was delivered via injection. For the 2 cases presented, the prolonged effect of the treatment with the heated lidocaine-tetracaine patch was an unanticipated response. Clearly, something other than anesthetic effect took place, and further study is warranted.

Conclusion

On the basis of its previous success managing SIS and the pathologic process of SIS, the heated lidocaine-tetracaine patch may be a viable treatment option. The 2 patient cases presented had stable exercise regimens and demonstrated the depth and duration of anesthesia exhibited by the heated lidocaine-tetracaine patch. Also, these cases support the potential utility of the heated lidocaine-tetracaine patch for the management of SIS and the need for further controlled studies. Pending the outcome of more studies, the heated lidocaine-tetracaine patch may be a viable early conservative management option for acute pain from SIS.

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