October 14, 2022

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Re: Proposed LCD on Sacroiliac Joint Injections and Procedures (DL39402)

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to express our strong support for coverage of sacroiliac interventions for pain management, and provide a detailed explanation of their importance to patients' quality of life.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved.

Significant relief of pain, improved quality of life, restoration of function, and decreased utilization of other healthcare resources are outcomes that should be readily available to patients covered by Medicare. When sacroiliac interventions are performed in a disciplined, responsible manner, they achieve outcomes that are clinically, socially, and economically worthwhile.

We commend the Medicare Administrative Contractors for inviting comments and presentations from physicians and experts earlier this year and giving appropriate and careful consideration to the evidence available about the important role these procedures play in treating patients with back pain. The result is a proposed local coverage determination that preserves and promotes access to sacroiliac joint injections but precludes coverage of radiofrequency ablation – a procedure proven to be safe and effective in providing pain relief and functional improvement in appropriately selected patients. We would like to offer the following comments to provide clarification and ensure that the procedures are made available to patients in a manner that will result in improved outcomes and quality of life.

NEUROANATOMICAL CONSIDERATIONS OF SIJ PAIN

The SIJ has both anterior and posterior innervation. The joint itself is innervated anteriorly by the lumbosacral trunks, obturator nerve, and gluteal nerves. The posterior sacroiliac joint complex (PSIJC) is innervated by the posterior sacral network (PSN), which consists of primarily the S1–S3 dorsal rami and, in some cases, fibers of the L5 dorsal ramus. **It is important to note that the intraarticular joint and the PSIJC are two different pain generators with different innervations**. **It logically follows that they should require different treatments to appropriately target the structures responsible for their respective generation of pain [1-4]. Intraarticular injections target anterior**

innervation. If pain is originating from the PSIJC, intraarticular injections will not result in significant improvements in pain or function. As currently proposed, patients with pain originating from the PSIJC have no interventional treatment options. ***Intraarticular SIJ injections do not diagnose or treat pain originating from the PSIJC.***

L5 DORSAL RAMUS AND SACRAL LATERAL BRANCH PROCEDURES

Diagnostic L5 Dorsal Ramus and Sacral Lateral Branch Blocks

Diagnostic L5 dorsal ramus and sacral lateral branch blocks involve injecting a small amount of local anesthetic onto the L5 primary dorsal ramus and S1-S3 dorsal rami lateral branches. These injections are used to evaluate whether anesthetizing the PSIJC mediates the patient's pain and to what degree. *They do not diagnose pain originating from within the SIJ.*

Indications

Small volume (≤0.5 mL per nerve) image-guided anesthetic blockade of the L5 primary dorsal ramus and per target for 1st-3rd sacral dorsal rami lateral branches are indicated to aid in the diagnostic work-up of LBP and must be considered prior to radiofrequency lesioning of these nerves. A positive response is at least 75% reduction of pain for the expected duration of the anesthetic, observed on 2 separate occasions. These blocks are appropriate when ALL of the listed criteria are met:

a) The patient reports primarily non-radicular, typically unilateral pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.
b) A physical examination typically demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, *i.e.,* at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (*e.g.,* greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.
c) Positive response to a cluster of at least 3 provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

L5 Dorsal Ramus and Sacral Lateral Branch Radiofrequency Neurotomy

L5 dorsal ramus and sacral lateral branch radiofrequency neurotomy (LBRFN) involves applying thermal radiofrequency energy to generate lesions along the L5 dorsal ramus and S1-S3 lateral branches aimed at coagulating the nerves responsible for PSIJC pain. *They do not treat pain originating from within the SIJ.*

Indications

Image-guided thermal radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches at S1, S2, and S3 are indicated for the treatment of sacroiliac pain when either of the listed criteria are met:

a) Clinical criteria for positive diagnostic anesthetic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (as above) are met AND pain has been

present for at least 3 months AND pain is severe enough to cause some degree of functional deficit despite other conservative treatment.

b) Posterior sacroiliac ligament complex pain has recurred after ≥ 50% improvement for ≥ 6 months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

Evidence in Support of LBRFN

Sacroiliac interventions are validated treatments for sacroiliac joint pain. Several high-quality systematic reviews have been published related to intraarticular sacroiliac joint injections [1] and PSIJC procedures [2-4]. These reviews are attached and present the outcomes reported in the literature, concluding that these procedures are effective for a substantial proportion of patients who are diagnosed accurately and treated with the procedure targeting the appropriate pain generator(s) as identified by diagnostic blocks.

The best available evidence on radiofrequency neurotomy of the L5 dorsal ramus and sacral lateral branches are two randomized controlled trials (RCT) that have demonstrated the efficacy of the procedure [6,7]. A pooled, between-group analysis of these RCTs revealed that those treated with radiofrequency neurotomy were four times more likely to achieve ≥50% pain reduction at three months compared with sham (proportion rate ratio/relative risk [4.84 (95% CI 1.19–19.73]) [2]. Despite the level of benefit shown in the pooled analysis, both these studies used patient selection criteria which is less than ideal for identifying PSIJC-mediated pain. Thus, the true benefit of radiofrequency neurotomy is likely superior in a properly selected patient population. Ultimately, there appears to be a therapeutic effect with treatment responder rates ranging from 32–89%, which is likely attributable to wide ranging variability in patient selection in the available studies for review [4]. Additionally, LBRFN has been shown to provide long-term pain relief, with studies reporting that 50-70% of patients achieved ≥50% pain reduction at up to 18-24 months [8,9], and pain relief can be reinstated with a repeat procedure [10]. It is also important to highlight during the current opioid crisis that LBRFN has been shown to reduce opioid dependency [11].

To date, there are three high-quality comprehensive reviews of the literature on LBRFN [2-4]. In 2015, King *et al.* concluded that there was "moderate" quality evidence for LBRFN, yet admittingly felt the current research base was limited by heterogeneity in the patient selection criteria. In 2019, Yang *et al.* reaffirmed that there exists "moderate" evidence to support efficacy and effectiveness of LBRFN for the treatment of PSIJC pain. Both King *et al.* and Yang *et al.* further delineated that PSIJC was a unique pain generator from the intra-articular SIJ, and both reviews conclude that radiofrequency neurotomy can provide relief for PSIJC pain.

In addition, a multidisciplinary, multi-society effort to develop appropriate use criteria for sacroiliac interventions concluded that intraarticular sacroiliac injections and thermal lateral branch radiofrequency neurotomy are appropriate treatments for appropriately selected patients. The multi-society expert rating panel consisted of members representing the American Academy of Orthopaedic Surgeons, American Society of Anesthesiologists, American College of Radiology, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, North American Spine Society, and Spine Intervention

Society. Panel members weighed the evidence and their clinical expertise in determining appropriateness of sacroiliac interventions for specific clinical scenarios [12].

Acknowledging the strength and quality of the evidence in support of the safety and effectiveness of LBRFN, the American Medical Association's Current Procedural Terminology (CPT®) Editorial Panel approved a Category I code that went into effect on January 1, 2020.

SACROILIAC JOINT INJECTIONS

The proposed LCD states under "Limitations" that sacroiliac joint injections to treat "axial spine pain" are investigational, and therefore, not considered medically reasonable and necessary. As written, the language could possibly be construed as excluding pain over the sacrum. Therefore, we recommend the language be revised to "axial spine pain primarily above the level of L5".

The undersigned societies appreciate the opportunity to provide these comments and would welcome the opportunity to again work with the Medicare Administrative Contractors to revise the coverage criteria included in the LCDs to ensure appropriate access to sacroiliac interventions for Medicare patients. If you have any questions or wish to discuss any of our suggestions, please contact Sarah Cartagena, Director of Health Policy at the Spine Intervention Society, at scartagena@spineintervention.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
Georgia Society of Interventional Pain Physicians
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology
Spine Intervention Society

Attachments:

- North American Spine Society. Coverage Policy Recommendations: Sacroiliac Joint Injections and Radiofrequency Ablation. 2020.
- MacVicar J, Kreiner DS, Duszynski B, Kennedy DJ. Appropriate use criteria for fluoroscopically guided diagnostic and therapeutic sacroiliac interventions: results from the Spine Intervention Society convened multispecialty collaborative. Pain Med 2017;18:2081-2095.
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Introduction

North American Spine Society (NASS) coverage recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 6/5/2019; information and data available after 6/5/2019 are thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology

The coverage recommendations put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, coverage recommendations reflect the multidisciplinary experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications

Low back pain (LBP) is the leading cause of global disability.[1] The sacroiliac joint (SIJ) represents a specific and identifiable cause of LBP. The SIJ is the cause of chronic LBP in 15-30% of patients, with a higher prevalence in older patients, those with a history of lumbosacral fusion, trauma, spondyloarthropathy, and/or maximal pain below the L5 vertebra.[2-14] Although no single physical exam maneuver has a high predictive value for diagnosing SIJ pain[2,15,16], the following criteria predict a positive response to a diagnostic intra-articular anesthetic block in 70-80% of patients: maximal pain below L5 and positive findings on at least 3 of 6 provocation tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression).[17-20] With the exception of acute inflammatory sacroiliitis or advanced arthritis, most patients will not demonstrate imaging abnormalities.[21] The reference standard for the diagnosis of SIJ pain remains a positive response to a fluoroscopically-guided intra-articular injection of local anesthetic. Several critical variables need to be accounted for when utilizing an SIJ injection, including the need for image-guidance and recording, an established false positive rate of around 20%, potential for extravasation of the anesthetic outside of the SIJ capsule, and the potential contribution of the SIJ dorsal ligaments to the LBP in question.[13,15,18,22,23]

The innervation of the SIJ and dorsal ligaments are important to understand when considering SIJ interventions. Just as the SIJ itself is a well innervated structure and a known cause of pain, the dorsal ligaments surrounding the SIJ are also well innervated by at least the L5 primary dorsal ramus, as well as the lateral branches of the 1st-3rd sacral dorsal rami.[24,25] Noxious stimulation of the dorsal SIJ ligaments do cause pain in healthy volunteers and anesthetic blockade of these nerves inhibits this pain.[24-26] Because the SIJ itself receives innervation from these dorsal nerves, as well as branches ventral to the sacrum, anesthetizing the dorsal nerve branches does not relieve pain from all aspects of the SIJ. Specifically, the more ventral joint surfaces and capsule may be unaffected by anesthetic blockade of the L5 dorsal ramus and sacral lateral branches. Thus, while a precisely placed intra-articular injection of anesthetic can eliminate pain from the SIJ intra-articular surfaces and capsule, it may fail to identify patients with pain from the dorsal ligaments. Similarly, while L5 dorsal ramus and sacral dorsal rami lateral branch anesthetic injections can eliminate pain from the dorsal and interosseous ligaments, they may fail to identify patients with pain from more ventral portions of the SIJ.[24-26] In summary, a SIJ intra-articular injection should not be considered interchangeable with sacral lateral branch blocks.

Taking all of these variables into account, the following sections provide utilization recommendations for diagnostic and therapeutic SIJ interventions, including SIJ intra-articular injections and SIJ dorsal nerve (L5 primary dorsal ramus and 1st-3rd sacral dorsal rami lateral branches) anesthetic blocks and radiofrequency ablation (RFA).

Clinical Criteria for the Procedures:

Item 1: Diagnostic intra-articular SIJ injections

Intra-articular SIJ injections are indicated to aid in the diagnostic work-up of low back pain when ALL of the listed criteria are met. All SIJ injections should be performed with some form of radiographic image guidance (eg, fluoroscopic, CT). The volume of injectate should

be limited to 2 mL and the inclusion of steroid with local anesthetic is not inappropriate. A diagnosis of SIJ pain is confirmed with at least 75% reduction of pain for the expected duration of the anesthetic used on 2 separate occasions.

a) Patient's report of nonradicular, typically unilateral, pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain
b) A physical examination typically demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (eg, greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.
c) Positive response to a cluster of at least 3 provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

Item 2: Diagnostic anesthetic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (S1–S3)

Small volume (<0.5 mL per nerve) image-guided anesthetic blockade of the L5 primary dorsal ramus and 1st-3rd sacral dorsal rami lateral branches are indicated to aid in the **diagnostic** work-up of LBP and must be considered prior to radiofrequency lesioning of these nerves. A positive response is at least 75% reduction of pain for the expected duration of the anesthetic used on 2 separate occasions.

These blocks are appropriate when ALL of the listed criteria are met:

a) Patient's report of nonradicular, typically unilateral, pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.
b) A physical examination typically demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (eg, greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.
c) Positive response to a cluster of at least 3 provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

Item 3: Therapeutic intra-articular SIJ injections

Image-guided intra-articular SIJ injections of corticosteroid with or without local anesthetic are indicated for the treatment of sacroiliac pain when ≥ 1 of the listed criteria are met[25]:

a) Clinical criteria for diagnostic SIJ injection are met (as above in item 1) AND pain has been present for at least 1 month AND pain is > 4/10 with functional limitation OR any pain level with functional limitation despite other conservative treatment.
b) SIJ pain has been confirmed with diagnostic intra-articular SIJ injections.
c) SIJ pain has recurred following a previous therapeutic SIJ injection which resulted in >50% pain relief for ≥ 3 months.
d) Advanced imaging (bone scan or MRI) demonstrate uptake or inflammation in the SIJ.
e) Patients with spondyloarthopathies such as ankylosing spondylitis.

Item 4: Radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (S1–S3)

Image-guided thermal radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches at S1, S2 and S3 are indicated for the treatment of sacroiliac pain when either of the listed criteria are met:

a) Clinical criteria for positive diagnostic anesthetic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (as above in item 2) are met AND pain has been present for at least 3 months AND pain is severe enough to cause some degree of functional deficit despite other conservative treatment.
b) Posterior sacroiliac ligament complex pain has recurred after ≥ 50% improvement for ≥ 6 months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

Rationale

Items 1 and 2

Patient Selection: The challenges associated with identifying patients with SIJ pain by history and physical exam alone has been well-studied.[26] No single historical finding is diagnostic of SIJ pain, but the following are common: unilateral pain, maximal pain below the L5 vertebrae, pain aggravated with sitting and transitions from sitting to standing, history of trauma, referred pain to the buttock, groin, thigh and occasionally below the knee.[3] The utility of physical exam findings has been more extensively evaluated in multiple studies, reviews and meta-analyses.[2,17-21,23,25,28-29] Studies agree that no single physical exam maneuver is reliable for diagnosis of SIJ pain[2,21], but a combination of provocative maneuvers can achieve a PPV of 70-80% for predicting at least a 50% improvement on a diagnostic intra-articular SIJ injection.[17,19,21,30] No combination of tests can predict an 80% or greater response.[2,29] History and physical exam cannot effectively differentiate between pain from the SIJ itself versus pain from the dorsal ligaments or both.[24] Based on the available evidence, it is reasonable to select patients for all types of diagnostic SIJ procedures on the basis of having maximal pain below the L5 vertebrae and at least 3 positive provocation maneuvers (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression) and lack of a better explanation for symptoms (eg, discogenic and/or radicular pain).[17,21-22,25,27]

Value of Radiographic Findings: While various imaging modalities can identify structural abnormalities of the SIJ, imaging abnormalities are not needed for a diagnosis of SIJ pain or for responsiveness to SIJ injections.[31] Plain radiographs and CT can identify late stage sacroiliitis or SIJ arthropathy. A positive bone scan can increase the likelihood that the SIJ is the source of pain, but a negative bone scan does not reduce the probability.[21] An MRI is more sensitive than bone scan or plain radiographs for early detection of sacroiliitis and may be useful for monitoring treatment response in patients with inflammatory spondyloarthropathy.[21,32,33] However, in the nonspondyloarthropathy population that makes up the vast majority of patients with LBP, neither MRI, nor any other imaging modality, has proven better than clinical selection to predict responsiveness to diagnostic SIJ injections. Furthermore, imaging findings have not been shown to be better than diagnostic injections for predicting responsiveness to therapeutic SIJ procedures. Thus, imaging is considered to be helpful in identifying patients who might benefit from further evaluations such as a diagnostic injection, though the absence of abnormalities on imaging does not negate the appropriateness of performing the procedure.

Image-guidance: Fluoroscopy remains the gold standard for diagnostic SIJ injections.[23] Nonimage guided "blind" injections successfully enter the SIJ capsule 12-22% of the time.[31,34] CT scan can be used for image guidance, but is less effective than fluoroscopy at capturing the escape of injectate from the joint to adjacent structures and cannot rule out concurrent intravascular flow.[23] In systematic reviews of SIJ interventions, fluoroscopic or CT guidance has been considered an inclusion criteria.[31,33,35,36] In experienced hands, U/S may be used effectively as image-guidance for therapeutic SIJ interventions.[37-39] However, U/S cannot verify intra-articular needle placement of the injectate, extravasation out of the joint capsule, or concurrent intravascular uptake.[23] Furthermore, cadaver studies have shown mixed results regarding the accuracy of U/S for intra-articular SIJ injections[40,41] and U/S is of limited utility in obese patients.[38,39]

Utility of Diagnostic Injections: History, physical exam and imaging studies are inadequate for confirmation of SIJ pain[23], at least in patients without spondyloarthropathy. Multiple studies and reviews have evaluated the utility of single and dual anesthetic blocks for the diagnosis of SIJ pain.[9,15,17,19,22-25,42] A single SIJ injection of anesthetic, with or without steroid, carries with it a false positive rate of at least 20%.[13,15,17,23] Due to the high false positive rates from a single injection and relatively low prevalence of SIJ pain, true confirmation of SIJ pain requires at least 75% improvement on 2 separate anesthetic blocks. Relaxing positive anesthetic block criteria from 75% down to 50% will significantly increase the observed prevalence of SIJ pain and increase treatment failures.[19,20,23,25] While studies are more limited regarding the diagnostic utility of anesthetic blocks of the L5 primary dorsal ramus and 1st-3rd sacral dorsal rami lateral branches for the diagnosis of SIJ dorsal ligament pain, the available evidence suggests similar criteria should be applied.[24,25,43] Furthermore, multi-site and multi-depth anesthetic blocks may be needed to completely anesthetize the dorsal and interosseous ligaments.[24,26,44]

Volume: The capacity of the SIJ capsule ranges from 0.6 to 2.7 mL. Injection volumes higher than 2.5 mL inclusive of contrast medium are unlikely to be retained in the joint and should not be considered target-specific, which is an essential criterion for diagnostic validity.[23] As is the case for lumbar medial branch blocks, the volume of anesthetic used for the L5 dorsal ramus and each sacral dorsal lateral branch should be < 0.5 mL per nerve, with lower volumes being more target-specific.

Anticoagulation: Reviews and consensus guidelines support that anticoagulant and/or antiplatelet medications should not be withheld for percutaneous SIJ interventions.[25,45] This is based on a lack of bleeding complications reported in the literature, absence of sensitive neural structures that could be damaged if bleeding did occur, and the known heightened risk of acute cardiovascular events when a prescribed anticoagulant or antiplatelet medication is discontinued.

Item 3

Therapeutic intra-articular SIJ injections: The utility of therapeutic intra-articular SIJ injections has been studied extensively, but with variable selection criteria and outcomes reporting. In the most comprehensive systematic review to date, the evidence is moderate for the effectiveness of therapeutic SIJ injections.[23] Patients with inflammatory spondyloarthropathy such as ankylosing spondylitis with associated sacroiliitis, may be the most responsive subgroup.[23,46,47] Based on the available data, including numerous observational and retrospective studies, along with limited RCTs, it is reasonable to expect that at least 50% of patients selected by the criteria described above will achieve ≥ 50% improvement in pain for at least 4-6 weeks.[23,31,42,48] Proportion of responders increases to 75% if inflammatory spondyloarthropathy present as the cause of SIJ pain.[23,46,47] Duration of response is highly variable and can range from 4 weeks to 9 months.[9,23,31] Retrospective data indicates that purely intra-articular placement of medicine may not be required for a positive therapeutic response to injection of corticosteroid[49-51] and incompetent SIJ capsules are common.[23] Recent studies also support that a therapeutic U/S-guided SIJ injection can produce a therapeutic response similar to fluoroscopically-guided injection[37,38], but most systematic reviews have included studies based on fluoroscopic or CT-guided injections.[23,31,33] A multispecialty collaborative panel of experts published appropriate use criteria for SIJ injections in 2017 and indicated that a SIJ injection with corticosteroid alone (ie, without anesthetic) is not recommended unless the patient has proven responsiveness previously to an image-guided SIJ injection including anesthetic.[25]

While the available data are mixed, it remains reasonable to offer coverage of therapeutic SIJ injections in those cases that fulfill the listed criteria.

Item 4

Radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches: Evidence regarding radiofrequency neurotomy for SIJ posterior ligament complex pain remains limited. Based on the available limited data, it is reasonable to estimate a response rate of 35-70% to achieve ≥ 50% improvement in VAS pain scores for at least 3 months, when selected by a positive response (≥ 50%) to diagnostic injection with anesthetic.[24,52,53] Positive response is probably both dependent on patient selection and technique.[24,53,54] While an optimal diagnostic/selection protocol has not been confirmed, a multi-specialty collaborative panel of experts published appropriate use criteria for SIJ interventions in 2017 recommending more stringent selection criteria of ≥ 75% temporary improvement in pain or function from anesthetic blocks for selection to thermal radiofrequency neurotomy.[43] Similarly, the optimal procedural technique has not been established, but appears to involve multiple lesions per nerve or bipolar lesioning due to variable anatomy of the lateral sacral branches[53,54], with single-site, single-depth lesions less likely to be effective.[26,44]

Acknowledging more limited data, it is reasonable to offer coverage for thermal radiofrequency neurotomy at the L5 dorsal ramus and S1-S3 sacral dorsal rami lateral branches for SIJ posterior ligament complex pain in those cases that fulfill the detailed listed criteria.

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Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

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Pain Medicine

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SPINE SECTION

Original Research Articles

Diagnosis and Treatment of Posterior Sacroiliac Complex Pain: A Systematic Review with Comprehensive Analysis of the Published Data

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Abstract

Objective. To assess the evidence on the validity of sacral lateral branch blocks and the effectiveness of sacral lateral branch thermal radiofrequency neurotomy in managing sacroiliac complex pain.

Design. Systematic review with comprehensive analysis of all published data.

Interventions. Six reviewers searched the literature on sacral lateral branch interventions. Each assessed the methodologies of studies found and the quality of the evidence presented.

Outcome Measures. The outcomes assessed were diagnostic validity and effectiveness of treatment for sacroiliac complex pain. The evidence found was appraised in accordance with the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of evaluating scientific evidence.

Results. The searches yielded two primary publications on sacral lateral branch blocks and 15 studies of the effectiveness of sacral lateral branch thermal radiofrequency neurotomy. One study showed multisite, multidepth sacral lateral branch blocks can anesthetize the posterior sacroiliac ligaments. Therapeutic studies show sacral lateral branch thermal radiofrequency neurotomy can relieve sacroiliac complex pain to some extent. The evidence of the validity of these blocks and the effectiveness of this treatment were rated as moderate in accordance with the GRADE system.

Conclusions. The literature on sacral lateral branch interventions is sparse. One study demonstrates the face validity of multisite, multidepth sacral lateral branch blocks for diagnosis of posterior sacroiliac complex pain. Some evidence of moderate quality exists on therapeutic procedures, but it is insufficient to determine the indications and effectiveness of sacral lateral branch thermal radiofrequency neurotomy, and more research is required.

Key Words. Posterior Sacroiliac Complex Pain; Lateral Branch Block; Radiofrequency Lateral Branch Neurotomy; Sacroiliac Joint

Introduction

The sacroiliac complex includes articulation between the sacrum and ilium, together with its capsule that forms

the sacroiliac joint proper (SIJ), the ligaments that support this joint anteriorly and posteriorly, parts of some regional muscles that cover the joint, and the nerves that supply these structures.

The nerve supply of the sacroiliac complex has been described variously as posterior (by the lateral branches of the S1–S3 dorsal rami with some fibers of the L4 and L5 dorsal rami), anterior (by branches of the lumbosacral trunk and the obturator and superior gluteal nerves), and both posterior and anterior [1–4].

"Sacroiliac pain" can arise from any of the structures of the sacroiliac complex. It is not a single, discrete entity but an assortment of pains that vary according to the anatomic structures from which they arise. This fundamental point seems not to have been appreciated by many authors who have written on the subject. The literature is confounded by equating, confusing, or combining SIJ pain and pain from other parts of the sacroiliac complex, particularly that from the posterior ligaments. The resultant confusion is illustrated by many papers which, in their titles, describe their topics as "sacroiliac joint pain" but then address pain stemming from the posterior ligaments or some other (extra-articular) structure(s). Accordingly, in this review, pain that arises from the sacroiliac region but has not been demonstrated conclusively to be generated from a specific structure will be designated "sacroiliac complex pain."

The SIJ was first described as a potential pain source in 1905 [5] and was addressed as a possible source of pain in papers published over subsequent decades [1,2,6]. SIJ pain was not defined precisely in the literature until 1994, when Fortin et al. showed that SIJ pain could be generated in asymptomatic volunteers by distending the SIJ with contrast medium and diagnosed by analgesic responses to image-guided intra-articular injections of local anesthetic [7,8]. The following year, Schwarzer et al. measured the prevalence of SIJ pain and demonstrated an association between SIJ pain and disruption of the anterior capsule of the joint made evident by leakage of contrast medium during arthrography of the joint [9]. The concept of sacroiliac complex pain, pain that arises in the sacroiliac region but not necessarily from the SIJ itself, has emerged in the literature over the last 15 years or so.

This review is focused on the diagnosis and treatment of pain arising in the posterior elements of the sacroiliac complex. In particular, it addresses the published evidence on local anesthetic injections around the sacral lateral branch nerves (sacral lateral branch blocks [SLBBs]) for diagnosis and sacral lateral branch thermal radiofrequency neurotomy (SLBTRFN) for treatment.

Methods

Six independent investigators, who are members of a multisociety Appropriate Use Criteria Task Force convened by the International Spine Intervention Society (ISIS), searched the scientific literature for publications on the validity of SLBBs for the diagnosis of sacroiliac pain and the effectiveness of SLBTRFN for the treatment of sacroiliac complex pain. They conducted digital searches using the search engine Ovid to explore the databases Embase, Medline, and EBM Reviews using the keywords sacroiliac, sacroiliac joint, sacroiliac complex, lateral branch blocks, radiofrequency lateral branch neurotomy, radiofrequency lateral branch denervation, radiofrequency lateral branch ablation, and variants of those terms with "radiofrequency" coming after "lateral branch." The searches encompassed all scientific papers published until January 2014. Foreign language papers were included. The only exclusions were nonhuman studies, conference abstracts, and single case reports unrelated to complications. When suitable papers were retrieved, the references of each were perused for relevant citations that had not been identified by the database searches.

The papers retrieved by the searches on SLBBs were separated from those on SLBTRFN. Each batch of papers was then sorted into two groups: primary publications (reports of studies that produced original data) and secondary publications (those not producing original data, such as literature reviews, editorials, and letters). Only primary publications are included in this review.

The primary papers on SLBBs were appraised by each of the investigators independently to assess their methodologies and the evidence they produced of the diagnostic validity of SLBBs.

The primary studies of SLBTRFN were then further classified into three categories: observational studies, pragmatic studies, and explanatory studies. Observational studies are defined as those that described the outcomes observed after the use of an intervention; note was taken of whether the observational study design was prospective or retrospective. Pragmatic studies are defined as those in which the outcomes of one intervention were compared with those of another intervention expected to have a useful effect. Explanatory studies are defined as those in which the outcomes of the intervention under study were compared with those of an intervention not expected to have a useful effect (a sham treatment). Explanatory studies show whether or not the studied treatment has an attributable effect (i.e., a therapeutic effect greater than the nonspecific effects of a sham treatment).

After being classified, the primary publications on SLBTRFN were appraised by each of the investigators independently. The investigators first considered the methodology of each study; then, they assessed the data produced as evidence of the therapeutic effectiveness of SLBTRFN. Categorical data were sought as the preferred evidence of effectiveness as data reflecting a binary decision such as success or failure of individual patients to achieve a set outcome (expressed as

success rates) can be collated to produce a body of evidence of effectiveness based on outcomes for specific patients. In this review, the primary outcome measure sought was success rates for the relief of pain arising in the sacroiliac complex.

The appraisals were done using instruments developed by the ISIS Standards Division based on the principles of the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of evaluating evidence. The GRADE approach provides systematic guidance for rating the quality of a body of evidence and grading the strength of recommendations for use of an intervention, based on consideration of factors such as risks of bias in the production of the data that contribute to the body of evidence and estimates of effect size. These instruments were used to maximize the reliability of assessment of studies and facilitate comparison of findings. The investigators then compared the results of their appraisals and discussed them to reach consensus on what the two bodies of evidence (on SLBBs and SLBTRFN) showed. The evidence was then evaluated in accordance with the GRADE system of rating quality of evidence [10].

Results

The relevant scientific literature was found to include two primary publications on SLBBs for the diagnosis of sacroiliac complex pain and 15 primary papers on SLBTRFN for the treatment of sacroiliac complex pain.

SLBBs

The two publications were appraised for evidence of the validity of diagnostic blocks of the sacral lateral branches.

The first paper, published in 2008, reported an experimental, randomized, controlled study to investigate the physiologic effectiveness of single-site, single-depth, sacral lateral branch injections [11]. Initially, 15 asymptomatic volunteers underwent fluoroscopically guided probing of their dorsal sacroiliac ligaments and injection of their SIJs with contrast medium until capsular distension occurred; the presence or absence of pain with each test was noted. The subjects were then allocated randomly to two groups for sacral lateral branch injections with 4% lidocaine (as the active intervention) or saline injections (as the control). The injectates were placed in single sites at single depths for each lateral branch. After 30 minutes, all had repeat ligamentous probing and capsular distension of the SIJ on the same side as the injections. The observations were that four subjects or 40% (95% confidence interval or CI_{95} 10–70%) of the active group and one subject or 20% (CI_{95} 0–55%) of the control group did not feel pain on repeat testing after the lateral branch injections; the overlapping confidence intervals show these results were not significantly different. Within the same manuscript, the results of a parallel anatomic study were reported. In this study, two nonembalmed cadavers were injected with green dye over the S1 and S2 lateral branches, and dissection was undertaken to quantify the degree of staining of the target lateral branch nerves. The authors found variability in the exact anatomic location of the sacral lateral branch nerves, and using single-site, single-depth injections, only four (36%) of the 11 identified lateral branch nerves were stained. These results show that both physiologically and anatomically single-site, single-depth SLBBs more often than not fail to infiltrate adequately the nerves they target, which seriously compromises their face validity as a diagnostic test.

In 2009, the same authors [12] published an experimental, randomized, controlled trial, this time designed to determine the physiologic effectiveness of multisite, multidepth sacral lateral branch injections. Initially, 20 asymptomatic volunteers underwent fluoroscopically guided probing of their interosseous and dorsal sacroiliac ligaments and the entry points for their SIJs, and their SIJs were distended with contrast medium. Again, the presence or absence of pain with each maneuver was noted. The subjects were then allocated randomly to two groups: 10 subjects received 0.75% bupivacaine (active) injections and 10 received saline (control) injections. All injections were performed with fluoroscopic guidance, targeted at the sacral lateral branches, and placed in multiple sites at multiple depths with each target receiving 0.2 mL of the allocated agent. On repeat ligamentous probing and capsular stimulation after 30 minutes, the presence or absence of discomfort with each maneuver was recorded again. The results were that seven patients or 70% (CI_{95} 42–98%) of the active group had insensate interosseous and dorsal sacroiliac ligaments and inferior dorsal SIJ vs none or one (for different ligaments) or 0–10% (CI_{95} 0–29%) of the control group. From these findings, the authors concluded that multisite, multidepth SLBBs are physiologically effective for the diagnosis of extra-articular posterior sacroiliac pain at a rate of 70%. It was also of interest that six of seven subjects (86%) who received 0.75% bupivacaine and had insensate posterior ligaments still retained the ability to feel repeat capsular distension. From these results, the authors concluded that multisite, multidepth SLBBs do effectively block the posterior ligaments of the sacroiliac complex but do not effectively block the SIJ. They interpreted this finding as physiological evidence that the SIJ is not exclusively innervated by the sacral lateral branches but must be innervated from both ventral and dorsal sources, as described in anatomical studies [1–3].

The evidence on multisite, multidepth SLBBs was found, in accordance with the GRADE system of rating evidence, to be of moderate quality [10]. That rating was determined because the positive evidence is from a single well-designed, controlled, experimental study. Readers can be moderately confident in the estimate of effect, and the true effect is likely to be close to that estimate, but there is a possibility that further research might show the effect is substantially different.

SLBTRFN

The 15 primary papers on SLBTRFN consisted of 13 observational studies and two explanatory studies. There were no pragmatic studies. Of the 13 observational studies, four were prospective and nine were retrospective reviews.

The literature was very diverse. The 15 papers described widely different criteria for patient selection and a variety of treatment techniques, which differed both in structures targeted and radiofrequency (RF) technologies used.

Criteria for patient selection in the 15 studies included different degrees of pain relief after injections of local anesthetic at various sites, single injections in some studies and dual (comparative) injections in others, and with the injection of a corticosteroid as well as the local anesthetic in many cases. Patients who had at least 75% relief on two occasions, following single-site, single-depth lateral branch blocks and local anesthetic blocks of the L5 dorsal rami, were selected for treatment for one of the explanatory studies [13]. Other patient selection criteria were relief after each of two comparative injections into the deep interosseous ligaments in one study [14], relief after comparative intra-articular or ligament injections for another study [15], and relief after intra-articular injections in the other 12 studies. The percentage relief required for a response to be considered positive also varied: 80% [16,17], 75% [18,19], 70% [14], and 50% in the remaining studies, except for one in which the percentage relief was not specified [20]. Patients were selected for treatment following double blocks in most studies and following a single block in four [18,20–22]. Steroid was injected with local anesthetic in the majority of the intra-articular injections and was also included in the injections into the deep interosseous ligaments [14].

Treatment targets described in the 15 studies included the SIJ itself, the sacral lateral branches, and the L4 and L5 dorsal rami. Radiofrequency lesions were placed over the posterior aspect of the SIJ in one study and did not directly target the sacral nerves [20]. In another, treatment targeted the lateral branches of the sacral dorsal rami in half of the patients, and the sacral lateral branches and the L4 and L5 dorsal rami in the other patients [21]. Lesions targeted the lateral branches of the sacral dorsal rami and the L5 dorsal rami in the other 13 studies, and the L4 dorsal ramus was also targeted in four of those studies [16,18,23,24].

Different RF technologies used included bipolar RF neurotomy in two studies [20,25], unipolar RF neurotomy in five studies [14–17,21], cooled RF neurotomy in six studies [13,18,19,22,26,27], and both unipolar and cooled RF neurotomy in two studies [23,24]. Unipolar RF neurotomy was used to treat the L4 and L5 dorsal rami in three of the studies in which cooled RF neurotomy or bipolar RF neurotomy was used to treat the sacral lateral branches [18,19,25].

Observational Studies

Three of the 13 observational studies of SLBTRFN reported only continuous data with results expressed as changes in group data recorded before and after treatment or no outcome data at all. Their results were not suitable for collation with those of studies producing categorical data which yielded success rates. The first was a pilot study of nine patients treated with bipolar RF neurotomy; the group's median pain score was 8/10 before treatment, and it was reduced to 3.5/10 at 1 month and 3 months after treatment and to 4.5/10 at 6 months and 12 months [25]. A study designed to determine whether pain distribution patterns predict outcome after SLBTRFN using unipolar electrodes reported favorable outcomes (defined as >50% reduction in pain intensity at a time not specified after treatment) for the majorities of patients in four groups with different pain maps, but group results were illustrated in a bar chart, and no numerical outcome data were provided [15]. In another study the results of 100 consecutive patients who had undergone SLBTRFN using either unipolar or cooled RF electrodes were expressed as rates of difficulty of the two techniques; no outcome data were reported as the paper was essentially a technical report on the methods used [27].

Ten of the 13 observational studies of SLBTRFN provided categorical data expressed as successful outcomes for specific patients, from which success rates could be calculated. These data were suitable for inclusion in a body of evidence of the effectiveness of SLBTRFN in practice. As outlined above, the methods of these 10 studies varied in criteria for patient selection, treatment targets, and RF technologies used. The general standard for successful outcome was defined as at least 50% reduction of the index pain for periods of between 2 months and 9 months after SLBTRFN. Some also reported results for complete relief of the index pain.

Bipolar RF was applied in one retrospective study, the earliest study of SLBTRFN [20]. Patients were selected on the basis of relief (extent not specified) following a single intra-articular SIJ injection. Strip-like lesions were placed over the posterior aspect of the joint using bipolar electrodes. Of 33 patients treated, 12 reported at least 50% pain relief for 6 months; thus, the success rate was 36% (CI_{95} 20–52%).

Unipolar RF electrodes were used in four of the 10 studies. Three studies of patients treated with unipolar RF were published in 2003 and 2004. Patients were variously selected on the basis of intra-articular blocks of the SIJ and subsequent blocks of the L4 and L5 dorsal rami, and the S1, S2, and S3 lateral branches [16], fluoroscopically guided deep interosseous ligament injections of local anesthetic and steroid [14], and a single intra-articular block [21]. The first was a pilot study reporting treatment retrospectively of nine nonconsecutive patients [16]. At review 9 months after treatment, eight of the nine patients or 89% (CI_{95} 69–100%) reported >50% relief of pain, and two of the nine or 22% (CI_{95} 0–49%) reported total pain relief. The second of these studies was also retrospective; it reported that

Table 1 Success rates of observational studies of SLBTRFN for achieving ≥50% relief of the index pain for 6 months (or the period nearest to that for which data were reported)

Study	Selection	RF Treatment	Follow-Up (Months)	Pain	Relieved ≥50% (%)
Ferrante et al. [20]	Unspecified relief after a single SIJB	Bipolar	6	12/33	36 (CI_{95} 20–52)
Cohen and Abdi [16]	80% relief SIJB, 50% after SLBBs	Unipolar	9	8/9	89 (CI_{95} 69–100)
Yin et al. [14]	>70% relief after two deep lig. injects	Unipolar	6	9/14	64 (CI_{95} 39–89)
Buijs et al. [21]	>50% relief after a single SIJB	Unipolar	3	24/43	56 (CI_{95} 41–71)
Speldewinde [17]	>80% relief after each of 2 SIJBs	Unipolar	2	12/16	75 (CI_{95} 54–96)
Kapural et al. [26]	>50% relief after each of 2 SIJBs	Cooled	3–4	13/27	48 (CI_{95} 29–67)
Karaman et al. [19]	>75% relief after each of 2 SIJBs	Cooled	6	12/15	80 (CI_{95} 60–100)
Stelzer et al. [22]	>50% relief after a single SIJB	Cooled	>4	70/126	56 (CI_{95} 47–65).
Cohen et al. [23]	≥50% relief after one set of SLBBs	Cooled or unipolar	6	40/77	52 (CI_{95} 41–63)
Cheng et al. [24]	≥50% relief after each of 2 SIJBs	Cooled or unipolar	6	28/88	32 (CI_{95} 22–42)

SIJB = sacroilaic joint block; SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

nine of 14 patients or 64% (CI_{95} 39–89%) had >50% decrease in visual integer pain score and 36% (CI_{95} 11–61%) had complete relief, maintained for at least 6 months after treatment [14]. In the third study, also retrospective, five of the 43 patients were lost to follow-up at review 12 weeks after treatment; of the others, 24 or 56% (CI_{95} 41–71%) reported at least 50% pain relief, and 10 or 23% (CI_{95} 10–36%) had complete pain relief [21]. A large case series was published in 2011 based on review of the records of unipolar RF treatments of cervical, lumbar, and sacroiliac pain over 10 years [17]. The series included 20 unipolar SLBTRFN procedures performed in 16 patients with sacroiliac pain, diagnosed by at least 80% relief of the index pain after each of two intra-articular SIJ blocks. A successful outcome was defined as at least 50% reduction of pain for at least 2 months after SLBTRFN. Categorical data were recorded by telephone contact between 6 and 36 months after treatment. The stated results were that 12 patients or 75% (CI_{95} 54–96%) reported having had at least 50% relief from pain for 2 months, and 7 or 44% (CI_{95} 20–64%) reported having had complete pain relief.

Cooled RF electrodes were used in three retrospective observational studies. In the first of these, 13 or 48% (CI_{95} 29–67%) of patients reported at least 50% pain reduction at follow-up 3–4 months after treatment, and three or 11% (CI_{95} 0–23%) had complete pain relief [26]. In the second, 12 of 15 patients or 80% (CI_{95} 60–100%) reported at least 50% decrease in pain scores at follow-up 6 months later [19]. In the third of these studies, the success rate for achieving at least 50% pain relief in the longer term (>4 months) was 77/126 or 61% (CI_{95} 52–70%) [22].

Both unipolar and cooled electrodes were employed, in different patients, in the other two observational studies, which were both retrospective. In the first study, 40 of 77 patients or 52% (CI_{95} 41–63%) achieved the set successful outcome of >50% pain relief at 6 months [23]. In the second of these studies, 58 patients underwent cooled RF techniques and 30 unipolar RF techniques; at review after 6 months, 28 of the patients or 32% (CI_{95} 22–42%) had >50% pain relief; analysis of the data showed no significant univariable relationship between RF technique and duration of pain relief [24].

The methods and data of these 10 observational studies are summarized in Tables 1 and 2.

Methodological issues cast some doubt on these results, as will be discussed later, but the observational

Table 2 Success rates of observational studies of SLBTRFN for achieving 100% relief of the index pain for 6 months (or the period nearest to that for which data were reported)

Study	Selection	RF Treatment	Follow-Up (Months)	Pain	Relieved 100% (%)
Cohen and Abdi [16]	80% relief SIJB, 50% after SLBBs	Unipolar	9	2/9	22 (CI_{95} 0–49)
Yin et al. [14]	>70% relief after 2 deep lig. injects	Unipolar	6	5/14	36 (CI_{95} 11–61)
Buijs et al. [21]	>50% relief after a single SIJB	Unipolar	3	10/43	23 (CI_{95} 10–36)
Speldewinde [17]	>80% relief after each of 2 SIJBs	Unipolar	2	7/16	44 (CI_{95} 20–64)
Kapural et al. [26]	>50% relief after each of 2 SIJBs	Cooled	3–4	3/27	11 (CI_{95} 0–23)
Stelzer et al. [22]	>50% relief after a single SIJB	Cooled	>4	29/126	23 (CI_{95} 16–30)

SIJB = sacroiliac joint block; SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

Table 3 Success rates of SLBTRFN for achieving at least 50% relief of the index pain as shown by the explanatory study of Cohen et al. [18]

Cohen et al. [18] Patients Selected by ≥75% Relief after a Single SIJB

Group	RF Treatment	Follow-Up (Months)	Pain	Relieved ≥50% (%)
Active group	Cooled	1	11/14	79 (CI_{95} 58–100)
$n = 14$	Cooled	3	9/14	64 (CI_{95} 39–89)
	Cooled	6	8/14	57 (CI_{95} 31–83)
	Cooled	12	2/14	14 (CI_{95} 0–32)
Control group	Sham	1	2/14	14 (CI_{95} 0–32)
$n = 14$	Sham	3	0/14	0
	Sham	6	0/14	0
Cross-over group	Unipolar	1	7/11	64 (CI_{95} 36–92)
$n = 11$	Unipolar	3	6/11	55 (CI_{95} 26–84)
	Unipolar	6	4/11	36 (CI_{95} 8–64)

SIJB = sacroiliac joint block; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

data do suggest that SLBTRFN can relieve sacroiliac complex pain, at least to some extent. The results of explanatory studies would be expected to clarify the issues.

Explanatory Studies

The two explanatory studies were randomized, controlled trials of SLBTRFN in which active treatment with cooled electrodes was compared to sham treatment.

The first explanatory study involved 28 adults, selected if they had at least 75% relief after a single intra-articular SIJ injection of bupivacaine and steroid [18]. They were allocated randomly to an active group of 14 patients and a control group of 14. Patients who did not respond to sham treatment were allowed to cross over and were offered treatment with RF denervation using unipolar technology. The patients were followed up at 1, 3, and 6 months after treatment, with the primary outcome measure being pain as assessed on a numeric rating scale (NRS). A successful outcome was defined as at least 50% pain relief at any stage. The categorical data provided for the primary outcome were as shown in Table 3.

These data suggest that SLBTRFN using cooled electrodes is more effective than placebo. They also show (again) that SLBTRFN using unipolar, thermal electrodes has outcomes similar to those of cooled RF. Overall, these data reinforce those of observational studies which show that SLBTRFN is effective for relieving pain arising in the sacroiliac complex, at least to some extent.

For the second explanatory study, patients were screened with two sets of single-site, single-depth local anesthetic blocks of the lateral branches of S1–S3 and of the L5 dorsal ramus. Patients who achieved 75% relief of their index pain after both blocks and had their index pain return were eligible for inclusion [13]. The 51 subjects enrolled were randomized on a 2:1 basis to receive SLBTRFN ($n = 34$) or a sham treatment ($n = 17$). Sham group subjects were allowed to crossover to SLBTRFN after 3 months. At follow-up reviews, patients

Table 4 Success rates of SLBTRFN for achieving at least 50% relief of the index pain as shown by the explanatory study of Patel et al. [13]

Patel et al. [13] Patients Selected by ≥75% Relief after Each of Two Sets of Single-Depth SLBBs

Group	RF Treatment	Follow-Up (Months)	Pain	Relieved ≥50% (%)
Active group	Cooled	3	16/34	47 (CI_{95} 30–64)
$n = 34$	Cooled	6	13/34	38 (CI_{95} 22–54)
	Cooled	9	20/34	59 (CI_{95} 42–76)
Control group	Sham	3	2/17	12 (CI_{95} 0–27)
$n = 17$				
Cross-over group	Cooled	3	7/16	44 (CI_{95} 20–68)
$n = 16$	Cooled	6	7/16	44 (CI_{95} 20–68)

SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

were assessed for pain, physical function, disability, global perceived effect, and quality of life using a number of instruments. Treatment success was defined as at least 50% decrease in the NRS pain score corroborated by either a 10-point decrease in the Oswestry Disability Index or a 10-point increase in the Short Form-36 scale for bodily pain. The results for pain were as set out in Table 4.

Prima facie, the raw data for the outcomes of active and sham treatment at 3 months seem to show that SLBTRFN using cooled electrodes is more effective than a placebo, although the 95% confidence intervals provided by the authors for the sham group outcomes (1–36%) overlap those of the active group (30–64%). The confidence intervals for sham treatment in Table 4 (0–27%) are as calculated by the authors of this review using the conventional, approximate formula, and they indicate that the active treatment was significantly more successful than the sham treatment at 3 months. The confidence intervals for the outcomes of the sham treatment group and those of the cross-over group at 3 months do overlap. Also, confidence intervals for the sham outcomes, calculated with adjustment for floor and ceiling effects on small proportions, results in a range of 2–34% which overlaps both the range for the active treatment at 3 months and the cross-over group at 3 months. If the figures in Table 4 for the results of active treatment and sham treatment at 3 months are taken in isolation, they do seem to show that SLBTRFN is better than a placebo, but the points outlined above leave that conclusion in doubt.

Taken overall, the evidence published to date suggests that SLBTRFN has some, although limited, effectiveness for the relief of pain arising in the sacroiliac complex. This evidence was found, in accordance with the GRADE system of rating quality of evidence, to be of moderate quality [10]. That rating was determined because the evidence includes data from two explanatory studies, with supporting evidence from observational studies. Readers can be moderately confident in the estimate of effect, and the true effect is likely to be close to that estimate, but there is a possibility that further research might show the effect is substantially different.

Discussion

The literature on SLBBs and SLBTRFN is not extensive. Although it is of moderate quality (in terms of GRADE ratings), it does not provide great endorsement for most of the sacral lateral branch interventions in current use.

The evidence on diagnosis by SLBBs is provided in two papers only. The summary of their findings is that multisite, multidepth SLBBs are target specific: They block the nerves they are intended to block. In other words, multisite, multidepth SLBBs have face validity for the diagnosis of posterior sacroiliac complex pain. There is no evidence of construct validity or predictive validity to augment the face validity of multisite, multidepth SLBBs. Single-site, single-depth SLBBs were shown not to have diagnostic validity, and no evidence of diagnostic validity was found for any other injections even though they are often used in practice.

The evidence on treatment by SLBTRFN comes from 15 studies. All used injections of local anesthetic, often with steroid, for patient selection, but none used multisite, multidepth SLBBs, which is the only injection technique shown to have any validity for the diagnosis of sacral lateral branch pain. It is not surprising, then, that in a substantial majority of cases, the relief after SLBTRFN was of limited degree and limited duration. A modal approximation of the outcomes is that about 50% of patients reported 50% relief 3 months after treatment, which is a far less than ideal outcome.

Thirteen of the 15 studies of effectiveness were observational studies which are all open to risks of bias because they lack control groups to account for confounding variables such as the placebo effect, the Hawthorne effect, the Rosenthal effect, regression to the mean, and effects of cointerventions (which were mentioned in six of the study reports); also, recall bias affects results recorded long after treatment (in one study, outcomes were elicited by telephone up to 3 years after treatment [17]), and losses to follow-up result in missing data which must be taken into account in calculating study results. All 13 observational studies could be criticized on methodological grounds, and their results must be interpreted as subject to resultant biases, the effects of which cannot be quantified.

Two of the effectiveness studies were explanatory, so their designs controlled for the risks of bias to which observational studies are subject. Unfortunately, neither used valid diagnostic injections. So, the sources of pains treated remain in doubt.

Nonetheless, despite the diversity of the 15 effectiveness studies in terms of patient selection criteria, treatment targets, and RF technologies applied, all patients had pains in the sacroiliac region, and those pains were relieved in many cases, at least to some extent. The data do not permit specific identification of the sources of the pains that were relieved, but the differences in selection criteria make it likely they were multiple. The known distributions of the S1, S2, and S3 lateral branches and the L4 and L5 dorsal rami suggest the structures from which they may transmit pain include the posterior elements of the sacroiliac complex (the posterior sacroiliac ligaments, the interosseous sacroiliac ligaments, inferior parts of the lumbar multifidus and erector spinae muscles, medial parts of the gluteus maximus muscle, and the posterior aspect of the sacroiliac joint) and the L5-S1 zygapophysial joint. Thus, on the evidence to date, pain relieved by SLBTRFN could be pain arising from any of those structures or a combination of them.

SLBTRFN would not be expected to abolish pain arising from the SIJ proper because anatomic [1–3] and

diagnostic [12] studies indicate that joint has both an anterior and posterior nerve supply. An intriguing conjecture is that perhaps SLBBs and SLBTRFN that produce partial but not total relief of pain may do so by blocking pain from the posterior capsule of the SIJ but not pain from the rest of the joint supplied by anterior nerves. Be that as it may, the authors of this review feel the best that can be said in the current state of knowledge is that pain relieved by SLBBs and SLBTRFN is likely to be pain from the posterior elements of the sacroiliac complex and its source(s) cannot be specified further, hence the title of this article.

Much of the literature reviewed reflected confusion of authors between pain generated from the SIJ and pain from other elements of the sacroiliac complex. This confusion should have been resolved, or at least reduced substantially, by the seminal diagnostic studies of Dreyfuss et al. who demonstrated clear differences between articular and extra-articular sacroiliac pain [12]. The confusion persists, however, and is still evident in papers published long after the Dreyfuss studies.

Further studies are required to enhance understanding of the roles that sacral lateral branch interventions may play in the management of sacroiliac complex pain. Future studies should explore the validity of multisite, multidepth SLBBs further using comparative local anesthetic agents and placebo controls to establish construct validity and the rates of false-positive and false-negative SLBBs, and precise therapeutic studies to establish their predictive validity or therapeutic utility. Future studies should also seek more information on the effectiveness of SLBTRFN, but if such studies are to be undertaken, it will be essential for the differences between the various potential sources of sacroiliac complex pain to be acknowledged and incorporated in their designs.

This review was undertaken as one contribution to a multisociety Appropriate Use Criteria Task Force convened by the ISIS. Its aim was limited to determining the scientific evidence of the validity of SLBBs for diagnosis and the effectiveness of SLBTRFN for treatment so these could be considered in the formulation of criteria for the appropriate use of interventions in the management of pain suspected of arising from the sacroiliac complex.

In addition to evaluating the quality of evidence on a given topic, the GRADE system assesses strength of recommendation for the use of interventions based not only on the quality of evidence but also on other factors such as risk-benefit analysis, cost-benefit analysis, access to services, and patient values and preferences [28]. The authors of this article have deliberately refrained from addressing strength of recommendations for use of SLBBs and SLBTRFN because they consider those recommendations will be more appropriately addressed by the appropriate use criteria to be published by the larger Task Force when it has considered all the findings of the various panels contributing to it.

Conclusions

The literature on sacral lateral branch interventions, as it stands in 2014, is sparse. The current body of knowledge is insufficient to support many interventions that are currently being used in practice.

The evidence that exists regarding the validity of SLBBs for the diagnosis of sacroiliac complex pain is rated as moderate in accordance with the GRADE system. In patients with sacroiliac pain, multisite, multidepth SLBBs have face validity for the diagnosis of pain arising from the posterior elements of the sacroiliac complex. Whether they also have construct validity and predictive validity remains to be seen.

The evidence to date of the effectiveness of SLBTRFN is also rated as moderate in accordance with the GRADE system. Fluoroscopically guided SLBTRFN seems effective for providing some relief of sacroiliac complex pain, but the evidence shows that relief is limited in extent and duration, and the indications for the procedure are unclear. SLBTRFN is not effective for blocking all pain from the SIJ itself because the joint is supplied by both anterior and posterior nerves; this latter point is not widely appreciated, and apparent confusion about it clouds the whole issue of interventions for sacroiliac complex pain.

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OXFORD

SPINE SECTION

Review Article

Appropriate Use Criteria for Fluoroscopically Guided Diagnostic and Therapeutic Sacroiliac Interventions: Results from the Spine Intervention Society Convened Multispecialty Collaborative

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Abstract

Objective. To provide an overview of a multisociety effort to formulate appropriate use criteria for image-guided injections and radiofrequency procedures in the diagnosis and treatment of sacroiliac joint and posterior sacroiliac complex pain.

Methods. The Spine Intervention Society convened a multisociety effort to guide physicians and define for payers the appropriate use of image-guided injections and radiofrequency procedures. An evidence panel was established to write systematic reviews, define key terms and assumptions, and develop clinical scenarios to be addressed. The rating panel considered the evidence presented in the systematic reviews, carefully reviewed the definitions and assumptions, and rated the clinical scenarios. Final median ratings, in combination with the level of agreement, determined the final ratings for the appropriate use of sacroiliac injections and radiofrequency neurotomy.

Results. More than 10,000 scenarios were addressed in the appropriate use criteria and are housed within five modules in the portal, available on the Spine Intervention Society website: Module 1: Clinical Indications and Imaging; Module 2: Anticoagulants; Module 3: Timing of Injections; Module 4: Number of Injections; and Module 5: Lateral Branch Radiofrequency Neurotomy. Within several of these modules, several issues of interest are identified and discussed.

Conclusions. Physicians and payers can access the appropriate use criteria portal on the Spine Intervention Society's website and select specific clinical indications for a particular patient in order to learn more about the appropriateness of the intervention(s) under consideration.

Key Words. Sacroiliac Joint; Lateral Branch Block; Posterior Sacroiliac Complex; Lateral Branch Radiofrequency Neurotomy; Intra-Articular Sacroiliac Joint Injection; Appropriate Use Criteria

Introduction

Being an innervated structure [1–5], the sacroiliac joint is a potential source of pain. Noxious stimulation of the joint in normal volunteers evokes back pain [6–9], and clinical studies have shown the sacroiliac joint to be the source of pain in about one in five patients with chronic low back pain [10–12].

Likewise, the posterior ligaments of the sacroiliac joint are innervated [13] and are, therefore, a potential source of pain. Noxious stimulation of these ligaments evokes

pain in normal volunteers [8,9], but no clinical studies have yet determined how often the posterior sacroiliac ligaments are the source of pain in patients with low back pain. Significantly for clinical purposes, studies have shown that local anesthetic blocks of the lateral branches of the sacral dorsal rami protect asymptomatic volunteers from noxious stimulation of the interosseous and dorsal sacroiliac ligaments, but not the sacroiliac joints [9].

Multiple studies have reported various success rates for relieving pain with injections of corticosteroids into the sacroiliac joint, but typically these studies had only a short duration of follow-up [12]. Success rates may have been overestimated in observational studies because such studies do not exclude the possibility of benefit from nonspecific or placebo effects [14]. On the other hand, in studies in which a valid diagnosis of sacroiliac joint pain was not previously made, success rates may have been underestimated by the inclusion of patients who do not have sacroiliac joint pain.

Several studies have attempted to relieve sacroiliac pain by performing radiofrequency neurotomy of the lateral branches of the sacral dorsal rami, with or without inclusion of the L5 dorsal ramus. For achieving at least 50% relief of pain, the reported success rate of this type of treatment is approximately 50% [15]. The majority of studies, however, selected subjects on the basis of their responses to intra-articular sacroiliac joint injections, rather than diagnostic blocks of the sacral lateral branches, which are the target of this therapeutic procedure; ironically, lateral branch blocks do not protect normal volunteers from sacroiliac joint pain.

Given these limitations in the literature, physicians are seeking guidance on how best to diagnose and treat SIJ and posterior sacroiliac complex pain, while insurers are wrestling with coverage decisions. For such situations, appropriate use criteria (AUC) can be developed in order to define areas of appropriate use, along with identifying potential overuse and underuse of procedures.

Methods

The objectives of the present AUC are 1) to provide physicians with a tool to assist in diagnosing and treating SIJ and posterior sacroiliac ligament pain utilizing image-guided injections and radiofrequency procedures and 2) to define for payers what is typically appropriate use of image-guided injections and radiofrequency procedures for these patients. This AUC does not address the entire spectrum of treatment options for sacroiliac pain.

The Appropriate Use Criteria Committee of the Spine Intervention Society adapted the RAND/UCLA Appropriateness Method (RAM) to guide development of appropriate use criteria [16]. RAM has been utilized extensively as a means to integrate the best available scientific evidence with the clinical judgment of experts.

Once the sacroiliac interventions topic was chosen, the Society invited other medical specialty societies, representing physicians involved in the care of patients with SIJ and posterior sacroiliac complex pain, to participate in a multisociety, multidisciplinary collaboration. The medical specialty societies that participated in the project with the Spine Intervention Society were the American Academy of Orthopaedic Surgeons, American Society of Anesthesiologists, American College of Radiology, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, and North American Spine Society. All invited societies appointed members to serve on both the evidence and rating panels.

The evidence panel was charged with 1) writing systematic reviews that summarized and evaluated the existing evidence [12,15]; 2) developing clinical scenarios that encompassed important clinical indications and interventional treatments to be evaluated by the rating panel (Appendix 1); and 3) formulating definitions (Appendix 2) and assumptions (Supplementary Data File S1, available online) to clarify terminology and scope. The rating panel was responsible for rating the clinical scenarios after carefully reviewing the definitions and assumptions and the evidence presented in the systematic reviews. All members of both panels disclosed potential conflicts of interest (Supplementary Data File S2, available online).

Two systematic reviews were completed in 2014 and served as the evidence base for the AUC project: One addressed diagnostic and therapeutic intra-articular sacroiliac injections [12], and the other addressed diagnostic and therapeutic posterior sacroiliac interventions, specifically lateral branch blocks and lateral branch radiofrequency neurotomy [15]. The authors of the two systematic reviews [12,15] appraised the evidence according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system of evaluating evidence, and in both cases the body of evidence was found not to be of high quality.

Without a solid, high-quality evidence base, the rating panel members were reliant to a large extent upon their own clinical experience in assessing the clinical scenarios regarding the appropriateness of the diagnostic and therapeutic image-guided injections and radiofrequency procedures for patients presenting with various combinations of clinical indications. Given the number of clinical indications and interventions, the rating panel members independently assessed more than 10,000 clinical scenarios, twice.

Each scenario was rated on a scale of 1–9, on which a score of 1–3 indicates that the intervention is inappropriate for the given clinical indications; 4–6 denotes uncertainty; and 7–9 assesses the intervention as appropriate.

Members of the rating panel rated the clinical scenarios once in March–April 2014, prior to a face-to-face meeting. Two weeks before the face-to-face meeting, members were provided with a report of their own ratings for each clinical scenario, along with anonymous ratings of the scenarios from the other members of the panel. The report also identified median ratings and whether there was agreement among reviewers.

The intention of the face-to-face meeting in May 2014 was to encourage discussion of scenarios with discrepant ratings or significant disagreement, not for the purpose of achieving consensus but in order to ensure that all members similarly understood the scenarios. Additionally, several definitions and many clinical scenarios were revised during the course of the meeting in order to reflect more accurately the intended indications referred to in the scenarios.

Following the meeting, members once again rated the scenarios in May–June 2014. The results of the second round of ratings were then circulated to the rating panel members for review and confirmation that their final, second round ratings accurately reflected their assessments, especially for the revised scenarios, which they had rated only once. The final median rating, in combination with the level of agreement, determined the final ratings for the appropriate use of sacroiliac injections and radiofrequency neurotomy.

Consistent with RAM, the definitions of levels of appropriateness and levels of agreement are as follows:

Levels of Appropriateness
- Appropriate = panel median of 7–9, without disagreement
- Uncertain = panel median of 4–6 OR any median with disagreement
- Inappropriate = panel median of 1–3, without disagreement

Levels of Agreement (for Panels of 11–13 Members)
- Agreement = no more than three panelists rate the appropriateness of the intervention for the scenario outside the three-point region (1–3, 4–6, 7–9) containing the median
- Neutral = more than three panelists rate outside the three-point region, but fewer than four ratings in an alternate three-point region
- Disagreement = four or more ratings in each extreme three-point region

Results

More than 10,000 scenarios were addressed in the AUC. It is not practical to present them all here. It is important, however, to provide an introduction to the five modules housed in the AUC Portal (Module 1: Clinical Indications and Imaging; Module 2: Anticoagulants; Module 3: Timing of Injections; Module 4: Number of Injections; Module 5: Lateral Branch Radiofrequency Neurotomy) and provide a breakdown of the indications and interventions contained in each module of the AUC (see Appendix 2). Within several of these modules, there are issues that merit some discussion and explanation.

Module 1: Clinical Indications and Imaging (Initial Injection)

The modules that address the appropriateness of sacroiliac injections and radiofrequency procedures for specific clinical indications and imaging are organized by primary location of pain, including pain localized to the SIJ, pain over the SIJ and referred into the leg, pain over the SIJ with referral into the groin, maximal ipsilateral pain above the L5 vertebra, and suspected acute spondyloarthritis. Within each module, important variables to consider comprise imaging findings, diagnostic physical examination testing, prior diagnostic injections, and potentially pertinent patient history.

When reviewing the location of pain as an independent variable, maximal pain above the L5 vertebra was negatively correlated with the recommendation for an SIJ injection. Other historical items, including the presence of spondyloarthritis, had minimal impact on the ratings. The rating panel placed more emphasis on physical examination findings. In scenarios with three or more positive provocation SIJ tests, the injection was given a high level of appropriateness regardless of the remainder of the scenario details. SIJ injections were also seen as appropriate for pain in the presence of one or two positive provocation tests depending on the other scenario variables. SIJ injections were not felt to be appropriate in subjects without a clinical exam or in those with no positive provocation maneuvers.

The rating panel placed little emphasis on imaging findings. There did not seem to be a clear distinction made between "degenerative changes" and "abnormal findings" on imaging studies despite these having been defined in the assumptions document. In fact, in some instances, when all other variables were equal, the presence of "degenerative" SIJ changes on imaging was more likely to generate a recommendation for an SIJ injection than the presence of "abnormal findings." This is felt to be an inconsistency and is likely the result of rater fatigue or a misinterpretation of the definitions of these different imaging findings.

When considering an initial injection in this module, the rating panel preferred injections with a combination of local anesthetic and steroid to injections of local anesthetic alone. This is likely reflective of practice patterns within the United States, given that the majority of societies involved comprise practitioners from the United States; initial injections are discussed in more detail below (see *Timing and Number of Injections*). For the initial injections that were addressed in this module, there were no recommendations to inject steroid without local anesthetic. In addition, there were no clinical criteria for which the panel agreed that it was appropriate to perform lateral branch blocks as a first intervention.

Module 2: Anticoagulants

The rating panel made clear recommendations to not withhold anticoagulant or antiplatelet medications prior to injecting the SIJ or lateral branches. This is likely based on the lack of bleeding complications reported in the literature combined with the absence of sensitive neural structures that could be damaged by a hematoma if bleeding were to occur. When anticoagulant medication is withheld, there is likely to be a greater risk posed by the condition for which anticoagulants were prescribed.

Modules 3 and 4: Timing and Number of Injections

The rating panel concluded that intra-articular injections of local anesthetic and steroid are an appropriate first intervention when pain has been present for more than one month, has an intensity of greater than 4/10, and is causing functional limitations, regardless of whether or not conservative therapy had been provided. In general, injections were considered appropriate for pain of lesser intensity and duration if the pain was causing functional limitation and conservative treatment had been provided.

As in Module 1, there were no scenarios for which an intra-articular injection of steroid alone was considered an appropriate first intervention. Also similar to Module 1, the rating panel preferred the injection of local anesthetic and steroid to an injection of local anesthetic alone as an initial injection. The median rating for an initial injection of local anesthetic alone was, in general, 1 point lower than the injection of local anesthetic and steroid. This did result in some scenarios in which injections of local anesthetic and steroid were considered appropriate, but injections of local anesthetic alone were considered uncertain, or injections of local anesthetic and steroid were considered appropriate with agreement, whereas injections of local anesthetic alone were considered appropriate without agreement.

Based upon rating panel discussion, we hypothesize that the justification for this phenomenon lies not in any lesser degree of appropriateness of first proceeding with a diagnostic injection without steroid; rather, it likely reflects the desire to limit the number of injections administered to a single patient. Physicians who perform a first injection that includes steroid are aware that they are administering a therapeutic agent to a patient who has not yet been diagnosed with sacroiliac joint pain. If the response to local anesthetic is positive, then they have saved the patient a subsequent office visit for an additional therapeutic injection, thereby reducing the travel burden to the patient, exposure to radiation, and reducing the albeit small risk of an infection from a subsequent injection. However, if the patient has a negative response to the local anesthetic, they have been unnecessarily exposed to steroid. The apparent inconsistency may well be an unintended consequence of payer limitations on the number of injections that will be reimbursed for a given patient's episode of care for suspected sacroiliac joint pain.

It was the opinion of the rating panel that injections of steroid with local anesthetic, injections of steroid alone, and lateral branch blocks would all be appropriate following an initial diagnostic injection that provided greater than 75% relief. Injections of local anesthetic and steroid were generally rated as more appropriate than other injections if the relief was greater than 50%. Further injections were generally not recommended if the pain relief was less than 50%.

The rating panel concluded that an injection of local anesthetic and steroid would be appropriate if there was at least 50% relief from an initial therapeutic injection or at least 75% relief from a subsequent injection, regardless of the duration of relief, and that an injection of steroid alone would only be appropriate if there was at least 75% relief for two months.

Module 5: Lateral Branch Radiofrequency Neurotomy

Two key factors were identified for the evaluation of indications for a lateral branch radiofrequency neurotomy (LBRFN): duration of symptoms and degree of pain relief obtained during blocks. The rating panel specified that patients should have symptoms for a minimum duration of two to three months prior to undergoing this procedure. Raters also clearly felt that obtaining less than 50% pain relief from diagnostic injections was insufficient justification to proceed with LBRFN. Increased percentage of pain relief and duration of symptoms both correlated with higher levels of appropriateness, although raters did not differentiate between 75% and 100% pain relief, which were treated as equivalent.

Similar trends emerged for consideration of repeat LBRFN. Repeat LBRFN was not deemed appropriate if the first LBRFN resulted in less than 50% pain relief or if the duration of effect was less than three months. Increasing the duration and percentage of pain relief resulted in higher levels of appropriateness, although the raters again did not discriminate between 75% and 100% pain relief. The type and sequence of block obtained (intra-articular vs lateral branch block) had minimal effect on the outcome and were most relevant for those with 50–75% pain relief and in those with only two to three months of symptoms.

Conclusion

Final ratings for the clinical scenarios are now available via a link to the AUC Portal of the Spine Intervention Society at http://www.spineintervention.org/?page=S1_AUC. Physicians can access the portal, review the assumptions and disclaimer, and proceed to select the module(s) of interest. By selecting the clinical indications for a particular patient, the physician will obtain information on the appropriateness of the intervention(s) under consideration. For those interested in reviewing the report that lists the median ratings and agreement for every clinical scenario, a PDF is available at http://www.spineintervention.org/?page=S1_AUC.

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Evidence Panel Members: Drs. Anil Sharma, Chair (Spine Intervention Society), Shihab Ahmed (Spine Intervention Society), Thiru Annaswamy (American Academy of Physical Medicine and Rehabilitation), Jamie Baisden (North American Spine Society), Asokumar Buvanendran (American Society of Anesthesiologists), Michael DePalma (Spine Intervention Society), Andrew Engel (Spine Intervention Society), Wellington Hsu (American Academy of Orthopaedic Surgeons), Wade King (Spine Intervention Society), Tim Lamer (American Academy of Pain Medicine), Devi Nampiaparampil (Spine Intervention Society), Nileshkumar Patel (Spine Intervention Society), Jeffrey Peterson (American College of Radiology), Jeffrey Summers (Spine Intervention Society).

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Rating Panel Members: Drs. Ray Baker (Spine Intervention Society), Asokumar Buvanendran (American Society of Anesthesiologists), Srinivas Chiravuri (Spine Intervention Society), Eduardo Fraifeld (American Academy of Pain Medicine), Mary Jesse (American College of Radiology), Milton Landers (Spine Intervention Society), Heidi Prather (North American Spine Society), Gwendolyn Sowa (American Academy of Physical Medicine and Rehabilitation), Claire Tibiletti (Spine Intervention Society), William C. Watters III (American Academy of Orthopaedic Surgeons).

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Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

Appendix 1 Definition and Derivation of Clinical Scenarios

For each module, multiple individual hypothetical scenarios were created by systematically combining the clinical feature specified in the title of the module with each of the features listed under “indications” in the table for each module. In turn, each of the features in the first column of indications was combined with each of the features listed in any subsequent column. The number of scenarios thus developed for each module was the arithmetic product of the number of features listed in each column. For each scenario, assessors would rate the appropriateness of each of the procedures listed in the table.

1. Clinical Indications and Imaging

Module 1.1 The patient has pain localized to the region of the sacroiliac joint

Indications			Procedures
Imaging	Diagnostic Tests	History	
No recent imaging Normal imaging of the lumbar spine and pelvis Normal imaging of the lumbar spine, but degenerative SIJ findings on pelvic imaging Degenerative changes in the lumbar spine and normal findings on pelvic imaging Degenerative changes in both the lumbar spine and SIJ Normal imaging of the lumbar spine and abnormal findings on pelvic imaging Normal imaging of the pelvis and abnormal findings on lumbar spine imaging Abnormal findings on imaging of both the lumbar spine and pelvis	No provocation testing performed Provocation tests, negative 1–2 provocation tests positive 3 or more provocation tests positive No diagnostic spine injection(s) Negative diagnostic spine injection(s)	No apparent inciting event History of pelvic trauma Spondyloarthritis History of fusion through L5-S1	Intra-articular SIJ injection of local anesthetic **with** steroid? Intra-articular SIJ injection of local anesthetic **without** steroid? Intra-articular SIJ injection of steroid alone?

SIJ = sacroiliac joint.

Module 1.2 The patient has pain located over the sacroiliac joint and referred into the lower limb

Indications			Procedures
Imaging	Diagnostic Tests	History	
No recent imaging Normal imaging of the lumbar spine and pelvis Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging Degenerative changes in the lumbar spine and normal findings on pelvic imaging Degenerative changes in both the lumbar spine and SIJ Normal imaging of the lumbar spine and abnormal findings on pelvic imaging Normal imaging of the pelvis and abnormal findings on lumbar spine imaging Abnormal findings on imaging of both the lumbar spine and pelvis	No provocation testing performed Provocation tests negative 1–2 provocation tests positive 3 or more provocation tests positive No diagnostic spine injection(s) Negative diagnostic spine injection(s)	No apparent inciting event History of pelvic trauma Spondyloarthritis History of fusion through L5-S1	Intra-articular SIJ injection of local anesthetic **with** steroid? Intra-articular SIJ injection of local anesthetic **without** steroid? Intra-articular SIJ injection of steroid alone?

SIJ = sacroiliac joint.

Module 1.3 The patient has pain over the sacroiliac joint and in the groin

Indications			Procedures
Imaging	Diagnostic Tests	History	
No recent imaging Normal imaging of the lumbar spine and pelvis Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging Degenerative changes in the lumbar spine and normal findings on pelvic imaging Degenerative changes in both the lumbar spine and SIJ on imaging Normal imaging of the lumbar spine and abnormal findings on pelvic imaging Normal imaging of the pelvis and abnormal findings on lumbar spine imaging Abnormal findings on imaging of both the lumbar spine and pelvis Abnormal findings on hip imaging	No provocation testing of SIJ performed Provocation tests of SIJ negative 1–2 provocation tests of SIJ positive 3 or more provocation tests of SIJ positive No diagnostic spine injection(s) Negative diagnostic spine injection(s) No provocation testing of hip performed Provocation tests of hip negative Provocation tests of hip positive No diagnostic hip injection(s) Negative diagnostic hip injection(s)	No apparent inciting event History of pelvic trauma Spondyloarthritis History of fusion through L5-S1	Intra-articular SIJ injection of local anesthetic **with** steroid? Intra-articular SIJ injection of local anesthetic **without** steroid? Intra-articular SIJ injection of steroid alone?

SIJ = sacroiliac joint.

Module 1.4 The patient has maximal ipsilateral pain above the level of the L5 vertebra

Indications			Procedures
Imaging	Diagnostic Tests	History	
No recent imaging Normal imaging of the lumbar spine and pelvis Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging Degenerative changes in the lumbar spine and normal findings on pelvic imaging Degenerative changes in both the lumbar spine and SIJ on imaging Normal imaging of the lumbar spine and abnormal findings on pelvic imaging Normal imaging of the pelvis and abnormal findings on lumbar spine imaging Abnormal findings on imaging of both the lumbar spine and pelvis	No provocation testing of SIJ performed Provocation tests of SIJ negative 1–2 provocation tests of SIJ positive 3 or more provocation tests of SIJ positive No diagnostic spine injection(s) Negative diagnostic spine injection(s)	No apparent inciting event History of pelvic trauma Spondyloarthritis History of fusion through L5-S1	Intra-articular SIJ injection of local anesthetic **with** steroid? Intra-articular SIJ injection of local anesthetic **without** steroid? Intra-articular SIJ injection of steroid alone?

SIJ = sacroiliac joint.

Module 1.5 The patient is suspected to have acute spondyloarthritis

Indications	Procedures
No provocation testing performed	Intra-articular SIJ injection of local anesthetic **with** steroid?
Provocation tests of SIJ negative	Intra-articular SIJ injection of local anesthetic **without** steroid?
1–2 provocation tests of SIJ positive	Intra-articular SIJ injection of steroid alone?
3 or more provocation tests of SIJ positive	
No laboratory data	
Laboratory data suggestive of acute spondyloarthritis	
Laboratory data not suggestive of acute spondyloarthritis	

SIJ = sacroiliac joint.

2. Anticoagulation

Module 2 The patient is taking anticoagulants

Indications	Procedures
Vitamins or herbal supplements with anticoagulant properties	Intra-articular SIJ injection of local anesthetic **with** steroid?
NSAIDS	Intra-articular SIJ injection of local anesthetic **without** steroid?
Single-dose daily aspirin	Intra-articular SIJ injection of steroid alone?
Antiplatelet agents other than single-dose daily aspirin	Lateral branch blocks?
Anticoagulation medication other than antiplatelet agents	Lateral branch radiofrequency neurotomy?
Anticoagulation and antiplatelet agents	

NSAID = nonsteroidal anti-inflammatory drug; SIJ = sacroiliac joint.

3. Timing

Module 3 The patient is being considered for an interventional procedure

Indications			Procedures
Pain Severity	Duration	Conservative Treatment	
<4 out of 10, but no effect on function	Less than 2 weeks	None	Intra-articular SIJ injection of local anesthetic **with** steroid?
<4 out of 10, and affecting function	2–4 weeks	Less than 3 months	Intra-articular SIJ injection of local anesthetic **without** steroid?
≥4 out of 10, but function not limited	1–2 months	At least 3 months	Intra-articular SIJ injection of steroid alone?
≥4 out of 10, and functional limitations	2–3 months		
	Longer than 3 months		

SIJ = sacroiliac joint.

4. Number of Injections

Module 4.1 The patient is being considered for a second intervention. A first injection produced relief of pain for the expected duration of action of the local anesthetic used

Indications Degree of Relief	Procedures
<50%	Intra-articular SIJ injection of local anesthetic **with** steroid?
≥50%	Intra-articular SIJ injection of local anesthetic **without** steroid?
≥75%	Intra-articular SIJ injection of steroid alone?
100%	Lateral branch blocks?

SIJ = sacroiliac joint.

Module 4.2 The patient is potentially eligible for an interventional procedure following dual diagnostic injections; each injection has provided relief of pain for the expected duration of action of the local anesthetic used

Indications				Procedures
First Diagnostic Injection		Second Diagnostic Injection		
Agents Used	Relief	Agents Used	Relief	
Local anesthetic	<50%	Local anesthetic	<50%	Intra-articular SIJ injection of local anesthetic **with** steroid?
	≥50%		≥50%	Intra-articular SIJ injection of local anesthetic **without** steroid?
	≥75%		≥75%	Intra-articular SIJ injection of steroid alone?
	100%		100%	Lateral branch blocks?
Local anesthetic with steroid	<50%	Local anesthetic with steroid	<50%	
	≥50%		≥50%	
	≥75%		≥75%	
	100%		100%	
Local anesthetic	<50%	Local anesthetic	None	
	≥50%			
	≥75%			
	100%			
Local anesthetic with steroid	<50%	Local anesthetic with steroid	None	
	≥50%			
	≥75%			
	100%			

SIJ = sacroiliac joint.

Module 4.3 The patient has had relief from a previous therapeutic injection and is being considered for a repeat therapeutic injection

Indications			Procedures
Previous Injection	Relief	Duration of Relief	
First therapeutic injection	<50%	<2 weeks	Intra-articular SIJ injection of local anesthetic with steroid?
Second or subsequent therapeutic injection	≥50%	2–4 weeks	Intra-articular SIJ injection of steroid alone?
	≥75%	1–2 months	
	100%	2–3 months	
		>3 months	

SIJ = sacroiliac joint.

5. Lateral Branch Radiofrequency Neurotomy

Module 5.1 The patient is being considered for lateral branch radiofrequency neurotomy. If performed, diagnostic blocks have provided relief for the expected duration of action of the local anesthetic used

Indications					Procedure
First Diagnostic Block		Second Diagnostic Block		Duration of Symptoms	
Site	Relief	Site	Relief		
None				Less than 2 weeks	Lateral branch radiofrequency neurotomy?
Sacroiliac joint	<50%			2–4 weeks	
Lateral branches	≥50%			1–2 months	
	≥75%			2–3 months	
	100%			More than 3 months	
		None			
		Sacroiliac joint	<50%		
		Lateral branches	≥50%		
			≥75%		
			100%		

SIJ = sacroiliac joint.

Module 5.2 The patient has had relief from a previous lateral branch radiofrequency neurotomy and is being considered for repeat treatment

Indications		Procedure
Previous Relief	Duration of Relief	
<50%	<3 months	Lateral branch radiofrequency neurotomy?
≥50%	3–6 months	
≥75%	6–12 months	
100%	>12 months	

Appendix 2 Fluoroscopically Guided Diagnostic and Therapeutic Sacroiliac Interventions: Clinical Scenario Definitions

Anticoagulant medication: medications designed to prevent blood coagulation. These medications include coumarins (warfarin, acenocoumarol, phenprocoumon), heparin and derivatives (heparin, low–molecular weight heparins, fondaparinux, idraparinux), direct factor Xa inhibitors (rivaroxaban, apixaban), and direct thrombin inhibitors (e.g., dabigatran, hirudin, lepirudin, argatroban, dabigatran).

Antiplatelet agents: any medication designed to reduce platelet aggregation and inhibit thrombus formation. These medications include irreversible cyclooxygenase inhibitors (aspirin), adenosine diphosphate receptor inhibitors (ticlopidine, clopidogrel, prasugrel, etc.), phosphodiesterase inhibitors (cilostazol), glycoprotein IIB/IIIA inhibitors (e.g., abciximab, eptifibatide), adenosine reuptake inhibitors (dipyridamole), and thromboxane inhibitors.

Conservative treatment: for the purpose of this document, conservative treatment refers to medical treatment (e.g., nonsteroidal anti-inflammatory drugs, activity modification, physical therapy) designed to avoid more invasive interventional procedures.

Diagnostic spine injection(s): fluoroscopically guided interventional procedure(s) performed for the purpose of diagnosing the source of pain. In the lumbar spine, these include intra-articular zygapophysial joint injections, lumbar medial branch blocks, lumbar spinal nerve blocks, and provocation discography.

Diagnostic hip injection(s): injections of local anesthetic directed toward or into structures that are suspected to be sources of hip girdle pain (e.g., hip joint injection for

intra-articular hip pathology, iliopsoas or trochanteric bursa injection for suspected bursitis).

Fluoroscopic guidance: use of fluoroscopy to guide the placement of needles and/or electrodes for invasive diagnostic and therapeutic procedures.

Fusion through L5-S1: any surgical procedure that involves fixating at least the lowest motion segment of the spine. This would include any discectomy procedure with interbody fusion, with or without the presence of posterior hardware (e.g., interspinous fixator, pedicle screws). In the case of anatomic variations (sacralized L5), fusion through L4-S1 would be included.

Hip pathology: any hip condition that can produce groin pain. This would include, but is not limited to, osteoarthritis of the hip, labral injuries, and iliopsoas bursitis.

Imaging: for the purposes of this document, imaging refers to any imaging modality that can adequately demonstrate pathology of the affected area. Examples would include plain radiographs, computed tomography scans, nuclear imaging (bone scan, SPECT), magnetic resonance imaging (typically with STIR images).

Recent imaging is defined as imaging obtained during the current episode to obtain information about the pathology of the affected area.

Degenerative changes on imaging are findings that may be related to an aging spine or joint that may or may not be symptomatic, including osteophytes, joint osteoarthrosis (or arthritis), disc desiccation and/or bulging, and loss of disc height. Findings on imaging that suggest pathological change may also be asymptomatic.

Abnormal findings on imaging of the lumbar spine might include acute fractures, acute disc protrusions or extrusions, high-intensity zones, bony edema presence on STIR or T2 fat saturated images, and/or positive bone scan with or without SPECT. In the case of patients with a prior L5-S1 fusion, abnormal imaging of the lumbar spine might include a pseudoarthrosis or adjacent-level disease.

Abnormal findings on pelvic imaging (includes bony pelvis, sacroiliac joint and related structures; excludes the hip joint) include bony edema presence on STIR or T2 fat saturated images and/or positive bone scan with or without SPECT.

Abnormal findings on imaging of the hip (includes acetabulum, hip joint, femoral head, and related structures) include radiographic findings consistent with full-thickness articular cartilage loss (subchondral cysts), severe osteoarthritis, labral injuries, iliopsoas bursitis, the presence of bony edema on STIR or T2 fat saturated images, and/or positive bone scan with or without SPECT.

Inciting event: traumatic or cumulative circumstance thought to be the cause of an injury.

Laboratory data: in the context of spondyloarthropathy, erythrocyte sedimentation rate and C-reactive protein levels are typically (though not always) elevated; a positive HLA-B27 is typical (though not diagnostic).

Lateral branch blocks (LBB): image-guided nerve blocks of the lateral sacral branches at S1–3, usually supplemented by an L5 dorsal ramus block.

Lateral branch radiofrequency neurotomy (LBRFN): image-guided thermal (not nonthermal or pulsed) ablation of the lateral sacral branches at S1–3, usually supplemented by ablation of the L5 dorsal ramus. For the purposes of this document, only radiofrequency ablative procedures are considered, not other neuroablative processes.

Lower lumbar/lumbosacral pathology: for the purposes of this document, this would include any condition in the lumbosacral spine that could reasonably be expected to refer pain to the area of the sacroiliac joint, gluteal area, or sciatic notch. This would typically be ipsilateral zygapophysial joint or disc pathology of the lowest two lumbar segments.

Pelvic trauma: any trauma that can disrupt the pelvic ring, including blunt force trauma from motor vehicle collision and childbirth.

Provocation tests: see below.

Referred pain: pain perceived in a location remote to its source. It is typically dull and aching in quality and deep, and its anatomical location is ill defined. The source of referred pain into the leg may be any structure in the lower back that has innervation, and referred pain should not be confused with radicular pain, which is caused by irritation of the dorsal nerve root or its ganglion. Lumbar radicular pain travels or shoots down the leg, typically in a narrow band, which feels near the surface and is often, but not necessarily, accompanied by evidence of radiculopathy (numbness and/or weakness).

Sacroiliac joint pathology: for the purposes of this document, this would include any condition in the sacroiliac joint structures that could be reasonably expected to cause pain.

Spondyloarthropathy: a seronegative inflammatory condition (e.g., ankylosing spondylitis, reactive arthritis, psoriatic arthropathy, inflammatory bowel disease) that affects the joints of the spine. The initial presentation is often pain over the sacroiliac joint and/or low back with no inciting event; typically a younger patient, may have a family history of spondyloarthropathy, pain and stiffness typically worse at night, in the morning, or with inactivity and improves with activity.

Spondyloarthritis: presence of a spondyloarthropathy or other systemic inflammatory condition that may cause sacroiliac joint inflammation (e.g., ankylosing spondylitis, gout, rheumatoid arthritis, psoriasis).

Suspected acute spondyloarthritis: recent onset of symptoms consistent with a spondyloarthropathy or other systemic inflammatory condition that may cause sacroiliac joint inflammation (e.g., ankylosing spondylitis, gout, rheumatoid arthritis, psoriasis). The typical patient would be young (usually younger than age 40 years) and present with stiffness and pain in the gluteal area and low back without an inciting event. This occurs more commonly in males and may include a family history of spondyloarthritis.

Provocation Tests

A positive provocation test is one that reproduces the patient's symptoms, suggesting that the joint that has been stressed may be the source of the patient's pain. Note that a torsional force is applied to both the sacroiliac joint and the hip joint during Patrick's test, and this test is therefore less able to distinguish between hip and SIJ pain.

SIJ Provocation Tests (Physical Exam Findings)

Test	Description	Photo
Patrick's Test	*This test applies tensile force on the anterior aspect of the SI joint.* The patient lies supine as the examiner crosses the same side foot over the opposite side thigh. A force is steadily increased through the knee of the patient, exaggerating the motion of hip flexion, abduction, and external rotation. The pelvis is stabilized at the opposite ASIS with the hand of the examiner.	
Thigh Thrust	*This test applies anteroposterior shear stress on the SI joint.* The patient lies supine with one hip flexed to 90 degrees. The examiner stands on the same side as the flexed leg. The examiner provides either a quick thrust or steadily increasing pressure through the line of the femur. The pelvis is stabilized at the sacrum or at the opposite ASIS with the hand of the examiner.	
Gaenslen's Test	*This test applies torsional stress on the SI joints.* The patient lies supine with the near side leg hanging off the table. The patient is asked to hold the opposite side knee in flexion. The examiner applies an extension force to the near side thigh and a flexion force to the opposite knee. The patient assists with opposite side hip flexion. This is performed bilaterally.	

ASIS = anterior superior iliac spine; SI = sacroiliac

Test	Description	Photo
Distraction	*This applies tensile forces on the anterior aspect of the joint.* The patient lies supine and is asked to place their forearm behind their lumbar spine to support the natural lordosis (not pictured). A pillow is placed under the patient's knees (not pictured). The examiner places their hands on the anterior and medial aspects of the patient's ASIS with arms crossed. A slow and steadily increasing pressure is placed through the arms and maintained.	
Compression	*This applies lateral compression force across the SI joint.* The patient is placed in a side-lying position, facing away from the examiner, with a pillow between the knees. The examiner places a downward pressure through the lateral aspect of the patient's top side ASIS and pelvis, anterior to the greater trochanter.	
Sacral Thrust	*This test applies anteroposterior shear stress on the SI joint.* The patient lies prone with legs extended. The examiner stands over the patient and provides either a quick thrust or steadily increasing pressure through the sacrum in an anterior direction.	

ASIS = anterior superior iliac spine; SI = sacroiliac

Hip Provocation Tests (Physical Exam Findings)

Test	Description	Photo
Log Roll	*This test moves the articular surface of the femoral head in relation to the acetabulum without stressing extra-articular structures.* The patient lies supine with hips and knees extended. The examiner passively internally and externally rotates the test leg while stabilizing the knee and ankle so that motion occurs only at the hip.	
Anterior Impingement Test	*This test places the femoral head in a flexed, adducted, and internally rotated position relative to the acetabulum.* The patient lies supine. The examiner passively flexes hip and knee to 90 degrees, then internally rotates and adducts the hip 10 degrees.	
FABER/ Patrick's Test	*This test applies torsional force to the hip joint in addition to a tensile force on the anterior aspect of the SI joint. The position also places the femoral head in a position that may reproduce pain if lateral impingement of the femoral head in relation to the acetabulum is symptomatic and structurally present.* The patient lies supine as the examiner crosses the same side foot over the opposite side thigh. A force is steadily increased through the knee of the patient, increasing hip external rotation. The pelvis is stabilized at the opposite ASIS with the hand of the examiner.	

ASIS = anterior superior iliac spine; SI = sacroiliac.

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Idiopathic Pelvic Girdle Pain as it Relates to the Sacroiliac Joint

Radiofrequency Ablation for Posterior Sacroiliac Joint Complex Pain: A Narrative Review

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Abstract

Radiofrequency ablation (RFA) of the sacral lateral branches targets the innervation of the posterior sacroiliac ligaments and posterior portion of the sacroiliac joint, also referred to as the posterior sacroiliac joint complex. This review assesses the published evidence on local anesthetic blocks for the diagnosis of posterior sacroiliac joint complex pain and the efficacy of RFA of the sacral lateral branches as a treatment. The current evidence suggests that RFA can provide relief of pain that originates from the posterior sacroiliac joint complex, but interpretation of this literature is limited by variability in patient selection criteria, the specific nerves targeted for ablation, and the types of RFA technology and technique utilized.

Introduction

The sacroiliac joint complex is a known cause of posterior pelvic girdle pain. The sacroiliac joint (SIJ) is a true diathrodial joint with a fibrous capsule and synovial fluid. The inferior portion contains articular cartilage while the superior portion is primarily ligamentous. The innervation of the intra-articular portion of the joint has been debated, with possible contributions anteriorly from the lumbosacral trunks, obturator nerve, and gluteal nerves, and posteriorly by the lateral branches of the S1-S3 dorsal rami and fibers of the L5 dorsal ramus in some cases.[1-3] Pain from the SIJ complex may arise from the posterior extra-articular elements in addition to or separate from the intra-articular portion of the joint. This complex includes the articular portion of the joint, overlaying dorsal ligaments, regional muscles, and nerves that supply these structures.[4]

Sacral lateral branch radiofrequency ablation (SLBRFA) has been introduced as a treatment option for pain arising from the SIJ complex. This procedure may be considered for patients with recalcitrant pain arising from the posterior SIJ complex, diagnosed by injections into the SIJ or along the sacral lateral branch blocks. Variability in the literature with respect to patient selection and procedural technique has resulted in conflicting reports of efficacy and effectiveness of SLBRFA. A prior meta-analysis in 2010 assessing the effectiveness of RFA for relieving SIJ pain demonstrated that 54%-69% and 42%-58% had >50% relief of their index pain at 3 and 6 months respectively.[5]

This narrative review of the published literature specifically addresses the outcomes literature related to SLBRFA and the effects of the various diagnostic and procedural techniques on the outcomes. In particular, we assess the current evidence germane to local anesthetic injections of the sacral lateral branches and SLBRFA of these nerves.

Methods

In June 2018, a digital search of the scientific literature was performed through PubMed and Google Scholar for publications on the validity of sacral lateral branch blocks (SLBB) for the diagnosis of sacroiliac pain and effectiveness of SLBRFA for treatment of SIJ pain. Keywords searched included lateral branch radiofrequency, SIJ, sacroiliac, lateral branch block, and variants of those terms. The searches encompassed all scientific papers published until June 2018.

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Publications that were excluded were conference abstracts, single case reports, technical studies, literature or anatomic reviews, letters, and editorials. The manuscripts were reviewed to assess their methodologies and evidence on the efficacy of SLBRFA. Additionally, the references within the manuscripts were reviewed as an additional step to ensure completeness of the literature search. Per the National Institutes of Health task force on low back pain recommendations, categorical "responder" analysis was used to calculate success rates in order to produce a body of preferred evidence of efficacy and effectiveness based on outcomes for patients with pain arising from the SIJ complex.[6] The primary outcome measure was the proportion of patients, calculated as success rates, who achieved ≥50% pain relief arising from the SIJ complex at 6 months or closest period in which data were reported. Studies that provided only continuous data, expressing changes as group data before and after treatment, or lack of outcome data, were excluded.

The included studies were categorized based on whether they were explanatory or pragmatic randomized controlled studies or were observational studies. Explanatory studies demonstrate whether the active treatment has greater efficacy than nonspecific effects of a sham treatment under controlled circumstances. Pragmatic studies compare the outcomes of the treatment of interest with another active treatment under real life conditions. Observational studies can be retrospective or prospective and describe the outcomes observed after an intervention without a control group comparison. Both pragmatic studies and observational studies provide information about the effectiveness of the treatment of interest.

Results

Sacral Lateral Branch Blocks (SLBB)

Two studies have assessed the SIJ anatomy and ability of diagnostic SLBBs to anesthetize the posterior joint complex and the intra-articular portion of the joint.[7,8] One study was performed in cadavers and the other was done on healthy individuals. They have not been repeated in patients with pain symptoms. These studies demonstrate that the SIJ complex functionally appears to have both anterior and posterior innervation and that SLBBs are capable of anesthetizing the posterior component (innervating extra-articular ligaments) but do not anesthetize the anterior component (innervating the intra-articular portion of the SIJ). These studies also demonstrate that single-site SLBB do not adequately target all of the sacral lateral branches due to anatomic variability. The results of these studies have meaningful implications in that in order to reliably anesthetize the sacral lateral branches to diagnose pain arising from the posterior SIJ complex, multisite, multidepth SLBB must be performed.

Sacral Lateral Branch Radiofrequency Ablation (SLBRFA)

Thirty-two studies of SLBRFA for the treatment of posterior sacroiliac complex pain were identified. Four were explanatory (efficacy) clinical trials, four were pragmatic (effectiveness) clinical trials, and 24 were observational studies. Of the 24 observational studies, 16 were retrospective and eight were prospective. The literature was diverse with variable selection criteria for SLBRFA, targeted nerve branches, and RFA techniques utilized.

Selection Criteria

Patient selection criteria for a majority of the studies included various levels of pain relief following an injection of anesthetic and corticosteroids into the joint. Only one study performed two sets of single-site, single-depth, anesthetic blocks of the sacral lateral branches and L5 dorsal ramus with at least 75% relief required for progression to SLBRFA.[9] Another study required only one set of single-site, single-depth SLBB with 50% relief in order to progress to SLBRFA.[10] Two studies performed two comparative intra-articular and/or deep interosseous ligament injections.[11,12] Other selection criteria included >70% relief with two comparative injections into the deep interosseous ligaments with anesthetic and corticosteroid.[13] The remaining 27 studies performed an intra-articular sacroiliac joint block (SIJB), with more than half of those injections including corticosteroid along with local anesthetic.

The percentage of relief required for a diagnostic response to be considered positive varied: 80%,[12,14,15] 75%,[9,16–18] and 50% in the remaining studies were defined as thresholds, except for three studies in which the required percentage of pain relief was not specified.[19–21] In one sham randomized controlled trial, patients were eligible for randomization if they had pain reduction of two or more points on the numeric rating scale (NRS) with one diagnostic, intra-articular anesthetic injection.[22,23]

Patients were selected for treatment in 18 of 32 studies following only one single diagnostic block. Most studies assessed response to diagnostic injection within hours whereas some assessments occurred at their next scheduled appointment, which could have occurred as far out as 6 months postintervention.[24] Five studies did not define when they assessed response to diagnostic injection.[20,22,25–27] Some of this variability related to assessment of corticosteroid effect rather than local anesthetic effect.

Targeted Nerve Branches

Treatment targets described included the L4 medial branch nerve and/or L5 dorsal ramus, sacral lateral branches, and the articular portion of the joint. Five studies targeted the L4 medial branch nerve[14,16,17,28,29] and one

study targeted the S4 sacral lateral branch.[22] Twenty-four of 32 studies included the L5 dorsal ramus and all studies included the S1-S3 sacral lateral branches except for two studies in which lesions were placed over the posterior aspect of the joint without targeting the sacral branches specifically[19] and another study in which the authors targeted the posterior interosseous sacroiliac ligaments.[21]

Radiofrequency Ablation (RFA) Technology

Various different types of RFA technologies were utilized among the studies reviewed including conventional monopolar RFA, conventional bipolar RFA, and cooled RFA. The Simplicity probe (Abbott, Austin, TX) was also used and is unique in that it is a multielectrode probe that utilizes both conventional bipolar and monopolar technology to create a strip lesion.[30] All cases used fluoroscopic guidance except for two studies that used computed tomography (CT) guidance[21,31] and one study that used endoscopy.[32]

Explanatory Randomized Controlled Studies

Three explanatory (sham-controlled) clinical trials were reviewed and one was excluded for this review as group data were presented without enough data to calculate success rates.[22] The excluded study compared 60 participants who were selected for cooled RFA or sham treatment based on a pain reduction 2 or more points on the NRS with one diagnostic, intra-articular anesthetic injection. Of note, 86.1% (62/70) participants reported positive relief with one diagnostic block making them eligible for randomization. The authors found no significant difference between the sham, treatment, and the crossover group in terms of mean pain reduction at 3 months.

One study reported on 12-month follow-up data from a study also included in this review.[33] Both of the original studies were randomized, controlled trials comparing cooled RFA to sham treatment. See Table 1.

In the first original study, patients were eligible for study enrollment if they received >75% relief of their index pain with two sets of single-site, single-depth, anesthetic blocks of the L5 dorsal ramus and S1-S3 sacral lateral branches.[9] A total of 51 participants were randomized at a 2:1 ratio to receive cooled RFA or sham treatment; participants in the sham group were allowed to cross over to cooled RFA after 3 months. Treatment success was defined by >50% improvement in NRS score and a 10-point improvement in 36-item Short Form Health Survey (SF-36) score or a 10 point improvement in Oswestry Disability Index (ODI) score. The original study included outcomes at 3 and 6 months in treatment group, crossover, and sham groups, and the subsequent publication reported on 12-month follow-up outcomes in the treatment group. At 3 months, 12% of participants in the sham group reported >50% relief of their index pain whereas the cooled RFA group reported 47% relief, which was statistically significant ($P = .01$). Similarly, there were statistically significant differences between the cooled RF group and the sham group at 3 months in mean improvement in NRS (−2.4 vs. −0.8 $P = .035$), SF-36 bodily pain (16 vs. −1, $P = .019$), SF-36 physical functioning (14 vs. 3, $P = .04$), and ODI (−11 vs. 2 $P = .011$) respectively. After the 3-month follow-up, unblinding occurred and 16 of the 17 participants in the sham group crossed over to receive lateral branch neurotomy. Accordingly, between group comparisons after this time point were rendered invalid. Of note, although only 12% of the sham group reported >50% relief before crossing over, after crossover and receiving neurotomy they did much better with 44% reported relief at 3 months. Additionally, in the initial cooled RFA group, >50% relief was still present in 52% of participants at 12 months, though there was no longer the sham group to compare to at this time point. See Table 1.

The second study included compared cooled RFA and sham treatment.[17] Patients who did not respond to sham treatment were allowed to cross over and were offered treatment using monopolar technology. Patients were randomized if they had >75% relief with one intra-articular corticosteroid and anesthetic injection 6 hours after injection and return of pain to baseline within 2 months. Twenty-eight patients were enrolled. Participants in the sham group were allowed to cross over into the monopolar RFA group at 3 months. At 1 month following treatment, 79% of participants in the active treatment group (cooled RFA) reported >50% relief of their index pain, and 14% reported this threshold of relief in the sham group ($P = <.01$). In the crossover group (monopolar RFA) at 1 month, 64% of participants reported >50% relief of their index pain. At 6 month follow-up, 57% in the cooled RFA group and 36% in the monopolar RFA group reported >50% relief of index pain at 6 months. Data for the sham group at 3 and 6 months were not analyzed, as only two participants had not crossed over by this time point. There were slightly higher success rates in participants who received cooled RFA compared to monopolar RFA, though the study was not appropriately powered or designed to detect a difference in the treatment effect between the two RFA technologies.

Pragmatic Randomized Controlled Studies

Two of four pragmatic studies were included for review whereas the other two were not included because of lack of or incomplete outcome data such that treatment success rates could not be calculated.[25,31] The first study randomized 30 patients who experienced >75% relief with one intra-articular SIJ anesthetic injection.[16] Fifteen participants received monopolar conventional RFA lesions of the L4 medial branch nerve, L5 dorsal ramus, and S1-S3 sacral lateral branches and the other 15 participants underwent one intra-articular corticosteroid injection

Table 1
Success rates for explanatory study by Patel et al[9,33] and Cohen et al[17] with >50% relief of index pain

		>50% Pain Response*		
	Treatment	3 mo	6 mo	12 mo
Patel et al[9,33]				
	Cooled RFA			
	Active	16/34 (47%) CI 95 = 30%-64%	13/34 (38%) CI 95 = 22%-54%	13/25 (52%) CI 95 = 32%-72%
	Crossover	7/16 (44%) CI 95 = 20%-68%	7/16 (44%) CI 95 = 20%-68%	
	Sham	2/17 (12%) CI 95 = 0%-27%**		
Cohen et al[17]				
	Cooled RFA		8/14 (57%) CI 95 = 31%-83%	
	Crossover		4/11 (36%) CI 95 = 8%-64%	

*n/N (%, 95% CI).
**Chi-square *P* value = .01 compared to active treatment.
CI = confidence interval; RFA = radiofrequency ablation

using fluoroscopic guidance. Participants in the corticosteroid injection group were allowed to cross over to RFA at 1 month. Follow-up data was collected at 1, 3, and 6 months post intervention. However, this study did not provide follow-up data for participants that crossed over (12 of 15 participants originally assigned to the corticosteroid injection group). Treatment success was defined by >50% reduction in the visual analog scale (VAS) pain score. Regarding primary outcomes, 3 of 15 participants (20%) who received intra-articular corticosteroid injection reported >50% relief of their index pain at 1 month but no further within-group analysis was performed due to an insufficient number of participants remaining at 3 and 6 months. In the RFA group, 73%, 60%, and 53% of participants reported >50% relief at 1, 3, and 6 months, respectively. Unfortunately this study did not provide any crossover data and is limited by a small sample size.[16] See Table 2 for full outcomes.

The second publication included reported on three pragmatic, multicenter, nonblinded, randomized clinical trials of patients with low back pain who underwent RFA and a standardized exercise program versus a standardized exercise program alone.[10] Participants were enrolled into three parallel trials depending on whether the authors considered them to have pain of lumbar facet joint, SIJ, or multifactorial origin but this review will focus specifically on the SIJ trial. Outcomes were reported at 3, 6 weeks, 3, 6, 9, and 12 months. Patients were selected for enrollment in the SIJ trial based on >50% relief with one set of single-site, single-depth anesthetic L5 dorsal ramus and S1-S3 SLBBs, with a total enrollment of 228 participants. The pre-specified minimal clinically important difference was defined as an NRS pain score improvement of two or more points or > 30%. Treatment success was defined as a pain intensity reduction of >30% from baseline in which 50/99 or 51% (confidence interval [CI] 95 = 40%-62%) in RFA group and 42/85 or 49% (CI 95 = 38%-60%) in standardized exercise group were reported at 6 months in the analysis published (*P* = .94). However, when these data are analyzed by intention to treat and participants lost to follow-up are considered treatment failures, 41% of participants in the RFA group compared to 26% in the exercise-only group reported treatment success as defined by the authors (*P* = .01); the details of this reanalysis of minimal interventional treatments for participants with chronic low back pain (MINT) trials data have been described previously.[34] The authors did not report enough data to calculate success rates based on a definition of >50% reduction in pain at 6 months. Although this study reported no significant difference between RFA and control groups, a difference was present in intention to treat analysis, which favored RFA and exercise compared to exercise only.[10] It must be noted that controversy surrounds this trial due to the methods of patient selection for RFA, RFA technique, and interpretation of the outcome data.[34,35] Patients were selected to undergo RFA if they had at least 50% pain reduction in response to a single-site, single-depth, SLBB. However, based on cadaveric study and study in healthy participants, this method is insufficient to anesthetize the sacral lateral branch nerves.[7] Patients randomized to RFA underwent the procedure using different technologies, one of which has been associated with inferior clinical outcomes in comparative study.[36] Additional details have been described in prior publications that have addressed the apparent shortcomings of MINT.[34,37,38]

Observational Studies

Of the 24 observational studies, 16 were retrospective and eight were prospective. Sixteen studies provided categorical data such that success rates could be calculated. The eight other studies were excluded for review for various reasons including providing only continuous data, expressing changes as group data before and after treatment, or not providing outcome data. Report of study outcomes range from a final endpoint of 2-9 months

Table 2
Success rates for pragmatic studies by Salman et al[16] and Juch et al[10] at 6 mo

Study	Selection Criteria	RFA Technique	Comparison Group	Follow-Up	Pain (Responders/Total)	Outcomes
Salman et al[16]	>75% relief after single SIJB	Monopolar	Single injection of corticosteroid into SIJ	6 mo	RFA (8/15) and unable to analyze control group due to insufficient number of participants	Proportion with >50% pain reduction RFA 53% (CI 95 = 28%-78%)
Juch et al[10]	>50% relief after single SIJB	Cooled or bipolar	Standardized exercise program	6 mo	RFA (50/99) and control (42/85)	Proportion with >30% pain reduction RFA 51% (CI 95 = 40%-62%) Exercise 49% (CI 95 = 38%-60%) **Intention to treat analysis** RFA 41% (CI 95 = 32%-51%) Exercise 26% (CI 95 = 18%-35%)

CI = confidence interval; RFA = radiofrequency ablation; SIJB = sacroiliac joint block

following SLBRFA. Table 3 provides a summary of the data from the observational studies that were included.

Monopolar conventional RFA was used in 6 of 16 observational studies.[13-15,21,39,40] Two studies were prospective in design.[21,39] Selection criteria for these studies varied, including either single or dual intra-articular SIJ injections, deep interosseous ligament injections with corticosteroid, or single intra-articular sacroiliac joint local anesthetic injection followed by one subsequent set of SLBBs including the L4 and L5 dorsal rami. Follow-up data collection varied from 2-9 months. Sample sizes ranged from 9-43 patients. Collectively, the treatment success rates varied from 56% to 89% based on our primary outcome. Of note, one study used CT guidance to target the posterior interosseous sacroiliac ligaments and L5 dorsal ramus.[21] This specific study reported 66% (CI 95 81-51) treatment success based on our primary outcome.

Bipolar conventional RFA was used in one retrospective observational study in which patients were selected for treatment following one intra-articular SIJB with corticosteroid and anesthetic.[19] Striplike lesions were placed over the posterior aspect of the joint using bipolar electrodes without including the L5 dorsal ramus. Multiple lesions were created in a repetitive "leapfrog" manner along the posterior SIJ. At 6 months, 12/33 or 36% (CI 95 20-52) reported treatment success based on our primary outcome.

Multielectrode conventional RFA was used in two studies by use of the Simplicity III probe.[24,30] This probe creates three monopolar lesions and two bipolar lesions along the sacral lateral branches. The L5 dorsal ramus was specifically included in one study using a monopolar lesion.[24] Six months data were reported in both of these studies and sample sizes varied from 16-77 patients. The success rates varied from 50% to 55% based on our primary outcome.

Cooled RFA was used in four retrospective observational studies in which patients received treatment following either 50% or 75% relief from one or two intra-articular SIJ injections, respectively.[18,27,41,42] Cooled RFA lesions were created at the L5 dorsal ramus and S1-S3 sacral lateral branches. One out of the four studies reviewed did not use corticosteroids in their diagnostic injection but performed dual, intra-articular SIJB with anesthetic only.[18] This study reported 80% treatment success rate based on our primary outcome at 6 months. The other three studies in which corticosteroids were used as part of the diagnostic injection reported success rates ranging from 48%-70% based on our primary outcome with follow up ranging from 3-6 months.

Monopolar conventional RFA was compared to cooled RFA in two retrospective studies, collectively the two groups in these studies that both received SLBRFA can be considered as a single observational cohort. Patients were selected for treatment in the first study be at least 50% relief associated with dual intra-articular sacroiliac joint injections with corticosteroid and anesthetic.[28] At 6 months, 40 of 77 (52%) reported >50% pain relief. In the second study, patients were selected for treatment if they received at least 50% pain relief following a single intra-articular SIJ injection with corticosteroid or a single set of single-site, single-depth lateral branch blocks.[29] At 6 months, 28 of 88 (32%) of patients experienced >50% relief. This study reported no significant difference in clinical outcomes when monopolar RFA versus cooled RFA was used.

Conventional multielectrode RFA was compared to cooled RFA in one retrospective study in which patients were selected by >50% relief with one intra-articular SIJB of ropivacaine.[36] Strip lesions were placed along the S1-S3 sacral lateral branches using conventional monopolar and bipolar technology and this was compared to cooled RFA lesions along the L5 dorsal ramus and S1-S3 sacral lateral branches. Of the 21 patients treated with bipolar lesions, 8 reported at least 50% pain relief for 6 months whereas 18 of 22 patients in the cooled RFA group experienced this threshold of pain relief. Thus, the success rates for bipolar RFA was 38% (CI 95 = 32-445) compared to 82% (CI 95 = 74%-90%) for

Table 3
Success rates for observational studies >50% relief of index pain for 6 mo or closest period in which data was reported

Study	Type	Selection Criteria	RFA Technique	Study Duration Study	Total n (Responders/Total)	Proportion with >50% Pain Reduction
Romero et al[39]	Prospective	>50% relief after single SIJB	Monopolar	6 mo	26/32	81% (CI 95 = 67%-95%)
Gevargez et al[21]	Prospective	Unspecified relief after a single SIJB	Monopolar	3 mo	25/38	66% (CI 95 = 81%-51%)
Cohen et al[14]	Retrospective	80% relief after single SIJB, 50% after SLBB	Monopolar	9 mo	8/9	89% (CI 95 = 69%-100%)
Yin et al[13]	Retrospective	>70% relief after two deep ligament injections	Monopolar	6 mo	9/14	64% (CI 95 = 39%-89%)
Buijs et al.[40]	Retrospective	>50% relief after single SIJB	Monopolar	3 mo	24/43	56% (CI 95 = 41%-71%)
Speldewinde[15]	Retrospective	>80% relief after two SIJBs	Monopolar	2 mo	12/16	75% (CI 95 = 54%-96%)
Ferrante et al[19]	Retrospective	Unspecified relief after a single SIJB	Bipolar	6 mo	12/33	36% (CI 95 = 20%-52%)
Anjana Reddy et al[24]	Retrospective	>50% relief after single SIJB	Multielectrode	6 mo	8/16	50% (CI 95 = 25%-75%)
Schmidt et al[30]	Retrospective	>50% relief after single SIJB	Multielectrode	6 mo	42/77	55% (CI 95 = 43%-66%)
Stelzer et al.[41]	Retrospective	>50% relief after single SIJB	Cooled	>4 mo	70/126	56% (CI 95 = 47%-65%)
Kapural et al[27]	Retrospective	>50% relief after two SIJBs	Cooled	3-4 mo	13/27	48% (CI: 95 = 29%-67%)
Karaman et al[18]	Retrospective	>75% relief after two SIJBs	Cooled	6 mo	12/15	80% (CI 95 = 60%-100%)
Ho et al[42]	Retrospective	>50% relief after single SIJB	Cooled	6 mo	14/20	70% (CI 95 = 50%-90%)
Cheng et al[29]	Retrospective	>50% relief after two SIJBs	Cooled or monopolar	6 mo	28/88	32% (CI 95 = 22%-42%)
Cohen et al[28]	Retrospective	>50% relief after single SLBB	Cooled or monopolar	6 mo	40/77	52% (CI 95 = 41%-63%)
Tinnirello et al[36]	Retrospective	>50% relief after single SIJB	Cooled or multielectrode	6 mo	Multielectrode (8/21) and Cooled (18/22)	Multielectrode 38% (CI 95 = 32-445) and Cooled 82% (CI 95 = 74%-90%)

CI = confidence interval; RFA = radiofrequency ablation; SIJB = sacroiliac joint block; SLBB = sacral lateral branch blocks

cooled RFA, which collectively demonstrated a success rate of 61% (CI 95 = 76%-46%) based on our primary outcome.

In summary, 14 of 16 observational studies were retrospective in nature with variation in RFA technology and selection criteria although majority of studies included patients based on relief with one or two intra-articular joint injections. However, these observational studies do show that SLBRFA relieves pain originating from the posterior SIJ complex with 13 out of 16 studies demonstrating >50% relief of index pain at 6 months but results must be interpreted with caution based on the aforementioned variation and selection criteria.

Discussion

This review aimed to present the current literature on SLBRFA, and to an extent that it affects selection criteria, the validity of diagnostic multisite, multidepth SLBBs. The current evidence on SLBBs is primarily based on two studies that demonstrate that multisite, multidepth SLBBs can target the intra-articular versus the posterior sacroiliac joint complex.[7,8] Although these studies were not done in individuals with painful pathology, they do serve to highlight that the sacral lateral branches are not the sole innervation of the SIJ. Specifically, one of these studies showed that painful stimulation from the IA portion of the SIJ was not relieved by blockage of the sacral lateral branches.[7] This has significant implications for this body of research as most patients selected based on inferior alveolar injection, and did not specifically evaluate the posterior ligamentous structures.

Studies conducted on SLBRFA that selected patients through injections targeting the IA portion of the SIJ may not be ideal. Unfortunately, this applies to the vast majority of published studies to date. Out of the 32 studies reviewed, 27 of the studies performed an intra-articular injection with or without steroids. Despite this limitation there does appear to be some positive effects

from SLBRFA, even when selected by this technique with the majority of studies demonstrating positive treatment outcomes, which suggests that selection by inferior alveolar injection does provide prognostic value. However, collectively the results are widely variable and overall modest; the use of the more anatomically appropriate multisite, multidepth SLBBs to select appropriate patients for SLBRFA may improve the success rate of this treatment. One study did demonstrate robust treatment outcomes when using SLBBs as one of the screening criteria.[9] However, even this study only used single-site, single-depth SLBB, which have been shown to not fully target the sacral lateral branches. Indeed, further outcome studies are needed to determine the prognostic value of multisite, multidepth SLBBs compared to other methods of selecting patients for SLBRFA.

In addition to the anatomically valid approach of using SLBBs as screening criterion for SLBRFA, other diagnostic criteria could be considered. Single anesthetic blocks have shown to have an high false positive rates compared to dual blocks when studied in the spine.[43] Given all the studies to date have only evaluated the prevalence of SIJ pain, not posterior ligament pain, it is impossible to know if this is a common or uncommon disease process. This has implications on the degree of rigor needed for diagnostic blocks, as diseases with low prevalence may need more rigorous diagnostic criteria. This is especially relevant because the placebo effect may actually be higher than the true prevalence. In other spine procedures this has led to the need for dual comparative blocks instead of single blocks for an accurate diagnosis. Furthermore, the addition of corticosteroids to an anesthetic block may also have effects on its diagnostic validity. This is concerning as the majority of studies used corticosteroids when selecting patients. It is theoretically possible that if more rigorous blocks were utilized, then better outcomes would ensue. However, it is also unclear how commonly this procedure should be done at all, given the lack of prevalence data.

Anatomic studies have also shown a high variability in the exact position of the sacral lateral branches.[6] This is problematic when applying a controlled small radiofrequency lesion to a nerve whose exact location is not known. This has led to studies comparing the outcomes from monopolar to cooled RFA techniques.[17,29] The results of these studies have been mixed; however, they all used intra-articular injections to select patients as opposed to SLBBs. It is therefore unclear if differences would have emerged using anatomically valid selection criteria. One recent cadaveric study looked at the percentage of lateral branches that would be captured by cooled RFA and found that adjustments in needle placement did affect capture rates of the lateral branches.[44] Another cadaveric study compared 3 monopolar versus 4 bipolar lesions and capture rates of the sacral branches.[45] The authors found that bipolar lesions more reliably captured the lateral branches with the potential of a 100% capture rate. These findings do help direct future studies toward more anatomically valid techniques that can appropriately lesion the targeted nerves.

The inability to ensure lesioning of the sacral lateral branches combined with poor selection rigor may help explain the variability and overall modest success rates of SLBRFA. Despite these significant limitations in the available literature, there appears to be a therapeutic effect of SLBRFA, with positive outcomes ranging from 32%-89% although majority of the reviewed studies were observational and uncontrolled in nature. Based on the body of literature with two placebo-controlled studies, two comparative studies, and multiple observational studies, this effect is beyond what one would expect due to a placebo or natural history.

Future studies assessing the prevalence of posterior ligamentous pain that is relieved with multisite, multidepth blocks are essential. Additionally, explanatory (sham-controlled) clinical trials on SLBRFA using rigorous selection criteria such as dual multisite, multidepth blocks are clearly needed to ascertain the true value of this procedure.

Conclusion

There is preliminary evidence from one cadaveric study and a study performed in healthy participants that suggest that use of multisite, multidepth SLBBs may target the posterior sacroiliac joint complex. There is moderate evidence to support efficacy and effectiveness of SLBRFA for the treatment of posterior SIJ pain. This literature is limited by the selection criteria used and ablation techniques implemented. As such, uncertainty remains concerning the expected magnitude and duration of pain relief following SLBRFA for the treatment of posterior sacroiliac complex pain.

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Review Article

Radiofrequency Ablation for Chronic Posterior Sacroiliac Joint Complex Pain: A Comprehensive Review

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Abstract

Radiofrequency ablation of the sacral lateral branches targets the innervation of the posterior sacroiliac ligaments and posterior portion of the sacroiliac joint. These structures are also collectively referred to as the posterior sacroiliac joint complex. This review will discuss current diagnostic block paradigms and selection criteria for sacral lateral branch radiofrequency ablation, varying techniques and technologies utilized for sacral lateral branch radiofrequency ablation, and updates on the clinical outcome literature. The current evidence suggests that sacral lateral branch radiofrequency ablation can provide relief for posterior sacroiliac joint complex pain, but the literature is limited by variability in selection criteria, the specific nerves targeted by radiofrequency ablation, and the types of radiofrequency ablation technology and techniques utilized in clinical outcome studies.

Key Words: Radiofrequency Ablation; Sacroiliac Joint; Lateral Branches; Block; Pain

Introduction

The sacroiliac joint complex (SIJC) is comprised of the articular portion of the joint, including bone, articular cartilage, and joint capsule, and the posterior extra-articular structures which includes the overlying dorsal ligaments, regional muscles, and tendons [1]. The sacroiliac joint (SIJ) is a true diarthrodial joint with a fibrous capsule and synovial fluid, and is thought to be primarily innervated anteriorly via the lumbosacral trunks, obturator nerve, and gluteal nerves, whereas extra-articular structures are primarily innervated posteriorly by the posterior sacral network (PSN) which is made up of the S1–S3 dorsal rami and fibers of the L5 dorsal ramus [2, 3]. Pain may arise from any of the structures comprising the SIJ independent from, or in addition to, any of the PNS posterior, extra-articular elements. The SIJ is a known cause of posterior pelvic girdle pain, with an estimated prevalence of 10–33% based on diagnosis by $\geq$75% pain relief with dual intra-articular blocks, while the true prevalence of pain from the extra-articular SIJC structures is not currently known [4].

Sacral lateral branch radiofrequency ablation (SLBRFA) has been introduced as a treatment option offered after the failure of noninvasive therapies. A systematic review analyzing pooled data regarding the effectiveness of SLBRFA reported a responder rate of approximately 50% of patients reporting >50% pain reduction at three months, which is inferior to the success rates for radiofrequency ablation (RFA) in treating

lumbar and cervical spine zygapophyseal joint pain when patients are selected by dual comparative medial branch blocks [1, 5, 6]. This may be a reflection of less refined patient selection criteria, procedural technique, and the technologies utilized.

This review offers an updated discussion on the factors to consider when evaluating SLBRFA for SIJC pain, including patient selection criteria, block paradigms for optimization of outcomes, and techniques and technologies utilized for SLBRFA, as well as a brief overview of the clinical outcome literature.

Methods

A search of the scientific literature was performed through PubMed and Google Scholar databases for publications on the effectiveness of SLBRFA for the treatment of SIJC pain. The searches encompassed works published until July 2020. Manuscripts were reviewed and assessed for methodology, patient selection criteria, SLBRFA techniques, technologies used, and patient reported outcomes. We included randomized and non-randomized comparative studies and non-randomized studies without internal controls. Conference abstracts, single case reports, technical studies, literature or anatomic reviews, letters, and editorials were excluded. The relevant scientific literature includes 39 studies on SLBRFA for the treatment of chronic SIJC pain. This search was an update on a previously published review on SLBRFA [7].

Block Paradigms and Selection Criteria

A validated diagnostic or prognostic test should effectively select patients for therapeutic interventions who are likely to experience a robust treatment response in association with the intervention. Most studies have used intra-articular joint injection as the reference standard for diagnosis and selection for SLBRFA [8]. This method lacks concept validity though, as extra-articular sources of pain exist, such as the posterior sacral ligaments and joint complex which is the intended target for SLBRFA. But SLB blocks and SLBRFA do not have effect on any structures of the SIJC that receive innervation anteriorly from the lumbosacral plexus, such as the SIJ itself [9]. Multisite, multi-depth sacral lateral branch (SLB) blocks are the only validated diagnostic procedure that identifies patients with pain originating from posterior structures deriving sensory innervation from the SLBs as indicated by prior study findings in which SLB blocks did not uniformly block pain associated with capsular distension of the SIJ [9]. This study establishes face validity and construct validity of multisite, multi-depth SLB blocks as a means of an accurate diagnosis of posterior sacral ligament complex pain. Aside from the challenges that arise from diagnosing SIJC pain by history, examination, and imaging findings, most studies have used intra-articular joint injection as the reference standard for diagnosis and selection for SLBRFA [8]. However, the prevalence of pain from these extra-articular sources is yet to be reported. This limitation is magnified upon review of the currently available literature and the selection criteria used to treat patients with SLBRFA.

Patient selection criteria in the majority of the studies include various pain relief thresholds used to define a "positive" block following an intra-articular injection of anesthetic and/or steroids. Out of the 39 studies reviewed, 34 studies performed an intra-articular SIJ injection with anesthetic as part of the selection criteria for SLBRFA, with more than half of those studies also using corticosteroids in the diagnostic block injectate. None of the studies reported using multisite, multi-depth blocks as part of their diagnostic algorithm. One study used dual SLB blocks and two studies performed single-site, single-depth, anesthetic blocks of the SLBs before progression to SLBRFA, although this approach has previously shown to inadequately anesthetize the posterior SIJC [10, 11]. Additionally, due to the inherent false positive rates of diagnostic blocks, dual blocks have been proposed as a more specific means of making an accurate diagnosis [12]. However, more than half of the patients were selected for SLBRFA following only one diagnostic block.

Given that the body of literature to date has only evaluated the prevalence of intra-articular SIJ pain using intra-articular injection as the reference standard, the prevalence of pain originating exclusively from structures innervated by the SLBs is unknown. In addition, the unknown false positive rates of SLB blocks and the lack of outcome studies for SLBRFA utilizing SLB blocks as selection criteria all limit interpretation of the available outcomes literature on SLBRFA.

Radiofrequency Technique and Technology

In the reviewed studies, there were inter-study differences in techniques and technologies utilized, as well as in the nerve branches targeted. Treatment targets in the majority of the studies included the S1–S3 sacral lateral branches and the L5 dorsal ramus. Less commonly included were the L4 medial branch and the articular portion of the joint, while one study targeted the S4 sacral lateral branch [13]. For context, a cadaveric study of the posterior SIJC innervation demonstrated S1 and S2 nerve contribution in all the specimens, S3 in 88%, L5 in 8%, and S4 in 4% [3].

There was heterogeneity in the RFA technologies utilized, which included conventional monopolar RFA, conventional bipolar RFA, cooled RFA, and a multi-electrode probe that utilizes both conventional bipolar and monopolar technology to create a strip lesion [14]. The two most common techniques used to denervate the SLBs were periforaminal lesioning, in which probes are placed at multiple clock face locations lateral to the

posterior sacral foramen, and strip lesioning, where a series of bipolar or monopolar lesions are created in a linear fashion medial to the SIJ and lateral to the sacral foramina.

Anatomic studies have shown high variability in the exact position of the SLBs [6]. This is problematic when applying a controlled small radiofrequency lesion to a nerve whose exact location is not known. A recent cadaveric study examined the percentage of SLBs that would be accurately lesioned by cooled RFA and found that adjustments in needle placement did affect rates of successful lesion of the SLBs [15]. Another cadaveric study that compared the capture rates of the SLBs, when using three different monopolar and four different bipolar RFA techniques, found that bipolar lesions more reliably captured the SLBs than monopolar, with the palisade and PSN lateral crest strip lesioning techniques showing the greatest likelihood of capturing 100% of the SLBs (both 97.5% likelihood), followed by a periforaminal bipolar and a cooled technique (both 92.5% likelihood) [16]. These findings do help direct future studies toward more anatomically valid techniques that can reliably denervate the SLBs.

Update on Clinical Outcome Literature

The literature has been limited by suboptimal selection criteria and variability in techniques that reliably create lesions that will denervate the SLBs, resulting in wide variability in outcomes within the literature and may underestimate success rates of SLBRFA. Despite these limitations, there appears to be a therapeutic effect with treatment responder rates ranging from 32–89% [7]. Success rates (the proportion of subjects with ≥50% pain reduction) can be calculated to produce a body of evidence on the efficacy and effectiveness of SLBRFA for patients with chronic SIJC pain. We summarize such, with a focus on randomized controlled trials (RCTs).

There are currently two explanatory (sham-controlled) trials with available success rates [11, 17]. Both studies randomized patients to receive cooled RFA or sham treatment, and both lesioned the L5 dorsal ramus and S1–S3 lateral branches. In the first study, patients were eligible for study enrollment if they received >75% relief of their index pain with two sets of single-site, single-depth, anesthetic blocks of the L5 dorsal ramus and S1–S3 sacral lateral branches. At three months, 12% of participants in the sham group reported >50% relief of their index pain, whereas 47% of the cooled RFA group reported this threshold of pain relief, which was statistically significant ($P = 0.01$) [11]. The between group comparison revealed that those who received SLBRFA, compared with sham, were four times more likely to experience ≥50% pain reduction at three months (proportion rate ratio/relative risk 4.00 [95% CI 1.04–15.43]). After the three-month follow-up, the majority of participants in the sham group crossed over to receive SLBRFA, disallowing further comparison. In the second study, patients were enrolled if they had >75% relief with one intra-articular steroid and anesthetic injection six hours after injection and return of pain to baseline within two months. This study was unique in that those who did not respond to sham treatment at three months were offered treatment with monopolar technology while the active treatment group received cooled RFA [17]. At one month following initial randomization, 79% of participants in the active treatment group (cooled RFA) reported >50% relief of their index pain, while 14% reported this threshold of relief in the sham group ($P = <0.01$). At the six-month follow up, 57% in the cooled RFA group and 36% in the monopolar RFA group reported >50% relief of index pain. Data for the sham group at three and six months were not analyzed due to a high crossover rate. Success rates were slightly higher in participants who received cooled RFA compared with monopolar RFA, though the study was not appropriately powered or designed to detect a difference in the treatment effect between the two RFA technologies.

There were two explanatory studies in which success rates could not be calculated [13, 18]. However, one study did not demonstrate any significant difference between sham, treatment with cooled RFA, and cross over group in terms of mean pain reduction at three months while another study demonstrated a significant difference in mean pain reduction at three months favoring multi-electrode probe RFA compared with sham.

There are two pragmatic studies in which success rates can be calculated [19, 20]. One pragmatic study did not show any difference between RFA and control treatment consisting of a standardized exercise program for sacroiliac joint pain [20]. However, recalculation of success rates according to intention to treat analysis demonstrates a significantly higher success rate associated with SLBRFA and exercise compared with exercise alone. Further methodological and data analysis flaws have been reported elsewhere, addressing the apparent shortcomings of this study particularly with regard to patient selection, block techniques, and SLBRFA techniques [21]. The other pragmatic study demonstrated success rates of 73%, 60%, and 53% of participants in the SLBRFA group at one, three, and six months, respectively [19]. This was statistically significant in favor of SLBRFA when compared with a single, intra-articular SIJ steroid injection.

When attempting to directly compare technologies utilized for SLBRFA, it must be noted that the majority of these studies are non-randomized cohort studies. One observational study demonstrated slightly higher success rates in outcomes for cooled RFA compared with monopolar RFA, although this study was not designed to detect an intergroup difference [17]. Another observational study comparing cooled RFA with monopolar RFA did not demonstrate any difference in clinical outcomes [22]. One observational study did demonstrate

superior treatment outcomes associated with cooled RFA compared with a conventional multi-electrode RFA probe [23]. Most recently, a retrospective study comparing a conventional multi-electrode RFA probe with monopolar periforaminal SLBRFA demonstrated success rates favoring the multi-electrode probe (71%) over periforaminal SLBRFA (65%), although overlapping confidence intervals cast doubt on the statistical significance of this finding [24]. These studies demonstrated a 69% success rate in reducing pain arising from the posterior SIJC for more than six months with SLBRFA.

Lastly, while the effectiveness of initial SLBRFA is based on limited evidence as detailed above, the ability of repeat SLBRFA to reinstate pain relief after an initial successful treatment is even less known. In a single retrospective observational study, repeated cooled SLBRFA has been shown to be beneficial with a greater mean duration of pain relief (nine months versus 5.5 months) compared with the first SLBRFA [25].

In summary, the highest quality evidence regarding the efficacy of SLBRA comes from two RCTs [11, 17]. Pooled, between-group comparison, revealed that those treated with SLBRFA were approximately four times more likely to achieve ≥50% pain reduction at three months compared with sham (proportion rate ratio/relative risk [4.84 (95% CI 1.19–19.73]). Aforementioned limitations in diagnostic enrollment criteria using techniques that have been shown to inadequately anesthetize the posterior SIJC and heterogeneity in technology and technique call into question the generalizability of the current literature [10].

Future Directions

Establishing the prevalence of posterior SIJC pain with pain that is relieved by multisite, multi-depth blocks is essential to furthering our understanding of SIJ region pain and optimizing treatment. Randomized, placebo-controlled studies using multisite, multi-depth SLB blocks to enroll patients for SLBRFA compared with sham treatments are needed to assess the efficacy of this procedure. Considering that there are inherent difficulties in performing sham or placebo-controlled studies, strong pragmatic or observational studies utilizing a more standardized and rigorous patient selection criteria may also provide useful insight. Utilizing a standardized and validated patient selection criterion and comparison of treatment outcomes between promising procedural techniques and technologies will help elucidate the true effectiveness and efficacy of SLBRFA in treating posterior SIJC pain.

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