

March 3, 2022

Juan L. Schaening, MD
First Coast Service Options, Inc.
Suite 100
2020 Technology Parkway
Mechanicsburg, PA 17050

Re: Multijurisdictional Contractor Advisory Committee Meeting Regarding Sacroiliac Joint Injections and Procedures

Dear Dr. Schaening,

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.

PREVALENCE

The prevalence of sacroiliac joint (SIJ) pain is 15-30%, with a higher prevalence in older patients, those with a history of lumbosacral fusion, trauma, spondyloarthropathy, and/or maximal pain below the L5 vertebra [1-13]. Thus, it is a condition that affects a significant number of patients.

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. For emphasis, 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 [14-17].

THE PROCEDURES AND THEIR INDICATIONS

Below is a brief description of each of the procedures and a list of indications. Many of the indications have been excerpted from the *NASS Coverage Policy Recommendations for Sacroiliac Joint Injections and Radiofrequency Ablation [18]*.

Diagnostic Intraarticular SIJ Injections

Diagnostic intraarticular SIJ injections involve injecting a small amount of local anesthetic directly into the sacroiliac joint cavity to anesthetize the articular nerves innervating the joint. These injections are used to evaluate whether anesthetizing the SIJ mediates the patient's pain and to what degree. *They do not diagnose pain originating from the PSIJC.*

Indications

All SIJ injections should be performed with some form of radiographic guidance (*e.g.*, fluoroscopy, CT). The volume of injectate should be limited to 2 mL and the inclusion of steroid with local anesthetic is reasonable. A diagnosis of SIJ pain is confirmed with at least 75% reduction of pain for the expected duration of the anesthetic, observed on 2 separate occasions. Diagnostic intraarticular SIJ injections are indicated to aid in the diagnostic work-up of low back pain 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.

Therapeutic Intraarticular SIJ Injections

Therapeutic intraarticular SIJ injections involve injection of corticosteroids into the SIJ to treat pain originating from the joint. *They do not treat pain originating from the PSIJC.*

Indications

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 [19]:

- 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 $\geq 4/10$ 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 $\geq 50\%$ pain relief for ≥ 3 months.
- d) Advanced imaging (bone scan or MRI) demonstrates uptake or inflammation in the SIJ.
- e) Patients with spondyloarthropathy (*e.g.*, ankylosing spondylitis, psoriatic arthritis).

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 $\geq 50\%$ improvement for ≥ 6 months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

THE EVIDENCE

Sacroiliac interventions are validated treatments for sacroiliac joint pain. Several high-quality systematic reviews have been published related to intraarticular sacroiliac joint injections [14] and PSIJC procedures [15-17]. 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. Regarding diagnostic injections, the NASS coverage policy recommendations provide a concise summary of the challenges involved in patient selection and the role of physical exam maneuvers, the questionable value of radiographic findings in ruling out SIJ pain, the importance of image guidance, the utility of diagnostic injections, injectate volume limits that ensure target-specificity, and the recommendation to continue anticoagulation therapy for patients on antithrombotics [18]. The recommendations also highlight that the evidence is “moderate” for the effectiveness of therapeutic SIJ injections, with at least 50% of patients selected by the criteria outlined expected to achieve at least 50% improvement in pain for at least 4-6 weeks [14,20]. For patients with inflammatory spondyloarthropathy, 75% can expect at least 50% improvement in pain [14,21,22].

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 [23,24]. A pooled, between-group analysis of these RCTs revealed that those treated with radiofrequency neurotomy were four times more likely to achieve $\geq 50\%$ pain reduction at three months compared with sham (proportion rate ratio/relative risk [4.84 (95% CI 1.19–19.73)]) [15]. 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 [17]. Additionally, LBRFN has been shown to provide long-term pain relief, with studies reporting that 50-70% of patients achieved $\geq 50\%$ pain reduction at up to 18-24 months [25,26], and pain relief can be reinstated with a repeat procedure [27]. It is also important to highlight during the current opioid crisis that LBRFN has been shown to reduce opioid dependency [28].

To date, there are three high-quality comprehensive reviews of the literature on LBRFN [15-17]. 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 [19].

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.

The undersigned societies appreciate the opportunity to provide these comments. The MPW societies would welcome the opportunity to again work with the Medicare Administrative Contractors to develop coverage criteria for inclusion 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 Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American College of Radiology
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
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.
- Kennedy DJ, Engel A, Kreiner DS, Nampiaparampil D, Duszynski B, MacVicar J. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. *Pain Med*. 2015;16(8):1500-1518.
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- Yang AJ, Wagner G, Burnham T, McCormick ZL, Schneider BJ. Radiofrequency ablation for chronic posterior sacroiliac joint complex pain: a comprehensive review. *Pain Med* 2021;22(Suppl 1):S9-S13. <https://doi.org/10.1093/pm/pnab021>

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- Yang AJ, McCormick ZL, Zheng PZ, Schneider BJ. Radiofrequency ablation for posterior sacroiliac joint complex pain: a narrative review. *PM R* 2019;11 Suppl 1:S105-S113. doi: 10.1002/pmrj.12200. Epub 2019 Jul 25. PMID: 31169356.

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Sacroiliac Joint Injections & Radiofrequency Ablation



**DEFINING APPROPRIATE
COVERAGE POSITIONS**



NASS Coverage Policy Recommendations

NASS Coverage Committee

North American Spine Society
Coverage Policy Recommendations
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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

*NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations **do not represent a "standard of care,"** nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient's needs as well as the doctor's professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.*

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 met²⁵:

- 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 spondyloarthropathies 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 $\geq 50\%$ improvement for ≥ 6 months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations **do not represent a "standard of care,"** nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient's needs as well as the doctor's professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.

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 pain²³, 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.

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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 $\geq 50\%$ 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 corticosteroid⁴⁹⁻⁵¹ 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 $\geq 50\%$ improvement in VAS pain scores for at least 3 months, when selected by a positive response ($\geq 50\%$) 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 $\geq 75\%$ 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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Additional Resources

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Author Disclosures

Aguwa, Okezie K.: Consulting: New Era Orthopaedics (B).

Baisden, Jamie : Nothing to Disclose

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Cowan, R. Scott: Speaking and/or Teaching Arrangements: LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement).

Dazley, Justin M.: Consulting: Clariance (C).

Dietze, Donald: Consulting: Joimax Spine (None, I have not received any remuneration to date.), Osseus Fixation Devices (B).

Easa, John E: Nothing to Disclose

Friedrich, Jason: Consulting: MCG Health (B, Divested as of 11/1/2018., Outside 12-Month Requirement).

Ghiselli, Gary: Board of Directors: Colorado Orthopedic Society (No compensation, volunteer position); Device or Biologic Distribution Group (Physician-Owned Distributorship): Impulse Neuromonitoring, Neurointerpretive Services (E), New Era Orthopedics (B); Private Investments: DiFusion (100,000 Shares, 9%).

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Holt, Timothy A.: Speaking and/or Teaching Arrangements: SI Bone (E, Paid directly to institution/employer).

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- Hullinger, Heidi M.: Trips/Travel: AAOS (American Academy of Orthopaedic Surgeons) (Travel Expense Reimbursement, Serve as AAOS delegate to AMA).
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- Khalsa, Kevin: Nothing to Disclose
- Kreiner, Scott: Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel expenses Reimbursed).
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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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Review Article

Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review

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Abstract

Objective. To assess the validity of fluoroscopically guided diagnostic intra-articular injections of local anesthetic and effectiveness of intra-articular steroid injections in treating sacroiliac joint (SIJ) pain.

Design. Systematic review.

Interventions. Ten reviewers independently assessed 45 publications on diagnostic validity or effectiveness of fluoroscopically guided intra-articular SIJ injections.

Outcome Measures. For diagnostic injections, the primary outcome was validity; for therapeutic injections, analgesia. Secondary outcomes were also described.

Results. Of 45 articles reviewed, 39 yielded diagnostic data on physical exam findings, provocation tests, and SIJ injections for diagnosing SIJ pain, and 15 addressed therapeutic effectiveness. When confirmed by comparative local anesthetic blocks with a high degree of pain relief, no single physical exam maneuver predicts response to diagnostic injections. When at least three physical exam findings are present, sensitivity, and specificity increases significantly. The prevalence of SIJ pain is likely 20–30% among patients that have suspected SIJ pain based on history and physical examination. This estimate may be higher in certain subgroups such as the elderly and fusion patients. Two randomized controlled trials and multiple observational studies supported the effectiveness of therapeutic sacroiliac joint injections.

Conclusions. Based on this literature, it is unclear whether image-guided intra-articular diagnostic injections of local anesthetic predict positive responses to therapeutic agents. The overall quality of evidence is moderate for the effectiveness of therapeutic SIJ injections.

Key Words. Sacroiliac Joint; Fluoroscopy; Injection; Local Anesthetic; Steroids

Introduction

The diagnosis of sacroiliac joint (SIJ) pain is challenging. Sacroiliitis, a common feature of spondyloarthropathies, can be identified by plain radiographs, magnetic resonance imaging (MRI), and radionuclide bone scanning [1]. Characteristic changes include sclerosis, erosions, and ankylosis [2]. Trauma can result in fractures or disruption of the joint. In the absence of serious trauma or confirmed sacroiliitis, the correlation between pain and

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findings on radiologic imaging is, however, poor. Changes seen on imaging may be asymptomatic and incidental as far as pain is concerned; and the SIJ can be a source of pain in the absence of any radiologic abnormality.

Distending the SIJ with injections of contrast medium results in pain in asymptomatic volunteers [3–5]. Injecting local anesthetic into the SIJ can also relieve pain localized to the SIJ area as well as pain radiating into the lower extremities [6].

Fluoroscopic guidance is essential for proper needle placement. One study found that, in patients who underwent blind SIJ injections, intra-articular needle placement was confirmed in only 22% in subsequent computed tomography (CT) scans [7]. In another study of “blind” injections, only five of 60 needles closely approximated the joint, and none had proper intra-articular placement [8].

Generally, ultrasound and CT can also be used for image guidance. However, ultrasound cannot verify intra-articular placement of the injectate and CT is less effective than fluoroscopy at capturing the escape of injectate from the joint to adjacent structures. Neither modality can rule out concurrent intravascular flow.

The capacity of the SIJ has been measured by injecting contrast medium until either resistance was met with a firm end-point, or extravasation from the joint was seen. The reported ranges have been: 0.8–2.5 mL [5], 1.0–2.5 mL [4], and 0.6–2.5 mL [3] in asymptomatic volunteers; and 1.0–2.5 mL [9] and 1.0–2.7 mL [6] in symptomatic patients, and the average volume of injection that produced capsular distention ranged from 1.08 to 1.6 mL. Intra-articular blocks during which local anesthetic are not retained within the joint and spreads into adjacent tissues cannot be target-specific, and target specificity, an essential criterion for validity, is unlikely when injecting volumes exceeding 2.5 mL [10].

Local anesthetic blocks of the lateral branches of the sacral dorsal rami protect volunteers from pain induced by stimulating the sacroiliac ligaments, but not from intra-articular pain [5], suggesting the joint has both ventral innervation and dorsal innervation. Local anesthetic blocks of the posterior innervation of the joint are, therefore, unlikely to relieve intra-articular pain completely [11].

The objectives of this review are to assess: a) the validity of diagnostic SIJ injections and b) the effectiveness of therapeutic SIJ injections. Nonfluoroscopically guided SIJ injections are not discussed given the low probability of accurate needle placement.

Methods

The literature on intra-articular SIJ injections was retrieved by searching PubMed and Embase Drugs and

Pharmacology through May 2015 using the terms: sacroiliac joint, fluoroscopy, injection, local anesthetic, steroids. Publications were divided into reviews or essays and studies yielding original data. Additional publications were identified from the bibliographies of retrieved publications [12–18].

Studies on diagnostic injections were organized according to the degree of pain relief required for a positive response, and the presence or absence of controlled injections. Each publication was independently appraised by each member of a team of reviewers with careful attention to methodological strengths and weaknesses. Each reviewer provided an appraisal and summary statement, using an evidentiary table developed by the International Spine Intervention Society’s Standards Division, emphasizing any particular virtues of the study and identifying any flaws. All reviewers participated in discussion of all studies until agreement was reached. Instead of grading individual studies for lack of quality, any crucial shortcomings were identified in the narrative that was developed for each study.

Results

The literature search yielded 39 articles on diagnostic SIJ injections, 15 articles on therapeutic SIJ injections, seven systematic reviews, four case reports on complications, and one article on the role of fluoroscopy. Both local anesthetic and steroid were injected in several studies. Studies that provided information about the immediate effect of local anesthetic were included in the diagnostic studies, and studies that reported information about the longer-term effect of steroid were discussed in the therapeutic section. To help identify trends in the literature, the studies were grouped into five categories based on the degree of relief obtained from local anesthetic injections. These included:

Placebo-Controlled Blocks

No studies were identified that utilized placebo-controlled blocks as selection criteria.

Controlled (Dual) Local Anesthetic Blocks

100% Relief from Local Anesthetic

No studies were identified that required 100% pain relief from an intra-articular injection of local anesthetic as a selection criterion.

At Least 75% Relief from Local Anesthetic

Initial injections of lidocaine were performed in 67 patients in the first of six studies in this category [19]. At least 75% relief from pain was reported 10 minutes after the injection by 19/54 patients [35% (95% confidence interval [CI]: 22–48%)]. The 19 subjects with an initial

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positive block underwent a second confirmatory block with bupivacaine, resulting in a positive response in 10/54 patients [19% (95% CI: 9–29%)]. A false-positive rate of 20% (95% CI: 8–32%) was calculated. None of seven provocation screening tests that were performed predicted a positive response to comparative blocks.

The goal of the second study was to document the prevalence of facet joint, discogenic, and SIJ pain in an outpatient spine clinic after conservative management [20]. Of 120 patients with lower back pain (LBP), 20 presented with symptoms suggestive of SIJ pain and six of these [30% (95% CI: 10–50%)] had positive responses to initial blocks with lidocaine. Two of the six patients, 2/20 [10% (95% CI: 0–23%)] of patients with suspected SIJ pain, had positive responses to confirmatory blocks with bupivacaine, and the false-positive rate was 22% (95% CI: 3–41%).

Both local anesthetic and steroid were injected in the remaining studies including one evaluating consecutive patients with buttock pain [21]. If patients had familiar pain with a slow injection of contrast medium and lidocaine into the SIJ, corticosteroid was also injected. Positive responses, with at least 80% relief, were reported by 16/48 patients [33% (95% CI: 20–46%)]. Confirmatory blocks with bupivacaine were performed in those with positive blocks, and were positive in 12/48 patients [25% (95% CI: 13–37%)], but were not performed in three patients (6%), who had persisting relief following the initial injections. Assuming a worst-case analysis with respect to the patients who did not undergo confirmatory blocks, the false-positive rate was 11% (95% CI: 1–21%). In this study, the diagnostic power of pain provocation tests was also examined. The sensitivity and specificity for three or more of six positive SIJ tests were 94% and 78%, respectively, with a likelihood ratio of 4.3. Similar results were reported in an earlier study, which appears to have been conducted on the same patient population [22].

Injections of local anesthetic and steroid were performed in a prospective study of patients diagnosed with presumptive sacroiliac pain, based on history, image findings, and positive responses to at least one of three provocation tests [23]. Of 232 patients with LBP without radiculopathy, 150 were diagnosed with presumptive SIJ pain. Patients were encouraged to have a second injection if they experienced pain relief of >75% for 1–8 hours after the first injection. Positive responses to a single injection were reported in 88 patients [59% (95% CI: 51–67%)]. Dual SIJ blocks confirmed the pain in 39 patients [26% (95% CI: 19–33%)]. Of those responding to a single block, 30 (34%) did not undergo a confirmatory second block.

The sixth study evaluated patients with prior history of lumbar or lumbosacral fusion, pain below L5 in a distribution compatible with SIJ pain and three of six positive provocation tests [24]. All patients had two injections, one with lidocaine and triamcinolone, and one with

bupivacaine and triamcinolone. Positive responses to both injections, with at least 75% relief from pain, were reported in 17 of 52 patients [33% (95% CI: 26–40%)]. Factors predictive of positive responses were unilateral pain, positive responses to four or more provocation maneuvers, and pain different from the preoperative pain.

At Least 50% Relief from Local Anesthetic

The first of two studies from a Dutch group reported that 27/60 [45% (95% CI: 32–58%)] of patients (responders) had at least 50% relief from both lidocaine and bupivacaine [25]. Positive responses to at least three of five SIJ provocation tests performed by an independent examiner were predictive of a positive response to local anesthetic blocks (PPV 77%; NPV 87%). There were five cases of transient sciatic palsy. This complication was avoided when repeat injections were performed with less anterior needle placement.

The second article differentiated pain referral areas between responders and nonresponders in the same patient population [26]. All patients who had at least 50% relief from comparative blocks and 80% of nonresponders had pain at Fortin's area, just inferior to the posterior superior iliac spine. An additional study was evaluated, but unfortunately no conclusions were possible given the proportion of patients who were investigated with intra-articular injections was not reported [27].

Uncontrolled (Single) Local Anesthetic Blocks

100% Relief from Local Anesthetic

No studies were identified that required 100% pain relief from an intra-articular injection of local anesthetic as a selection criterion.

At least 75% Relief from Local Anesthetic

In one study, a diagnosis of SIJ syndrome was made in patients who had at least 80% relief from pain after a local anesthetic block and at least 80% relief of pain for at least 2 weeks from subsequent injections of steroid and local anesthetic [28]. Positive responses to local anesthetic blocks were reported in 81/194 [42% (95% CI: 35–49%)] of patients, and 54/194 [28% (CI 95% 22–34%)] responded to intra-articular injections of steroid and local anesthetic.

Single diagnostic blocks with at least 75% relief were used to estimate the prevalence of SIJ pain in a sample of LBP patients [29]. All patients had previously undergone controlled blocks of the lowest two zygapophysial joints, which provided a form of anatomical control. Positive responses were recorded in 13/43 [30% (95%

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CI: 16–44%]) of patients, including four [9% (95% CI: 0–18%)] who had complete relief from pain. A ventral capsule tear was demonstrated in 42% of patients, and there was a positive but weak association between this finding and positive blocks. Exact reproduction of pain during the injection did not predict a positive response and, with the exception of groin pain, pain patterns did not predict a response, nor did physical examination findings.

The incidence of SIJ dysfunction in 50 patients with LBP, positive intervertebral disc findings on CT scan or MRI, and positive responses to at least three provocation tests, was assessed with intra-articular SIJ injections of local anesthetic and steroid [30]. The mean baseline visual analog scale (VAS) pain score was 7.8 and the mean score 30 minutes after injections was 1.3. Categorical data were not provided.

DePalma and coworkers published seven articles in 2011 and 2012, based on retrospective chart review of consecutive patients with LBP [31–37]. Of 378 cases (358 patients), definitive diagnostic spinal procedures, including provocation discography, facet joint blocks, and SIJ blocks, were performed on 170 (160 patients) [36]. Of these patients, 31 [18% (95% CI: 12–24%)] had at least 75% relief from a single injection of local anesthetic into the SIJ. The proportion of patients suspected to have SIJ pain who had positive responses to injections of local anesthetic is unknown, as the number of SIJ injections performed was not reported.

A positive response to sacroiliac injections was associated with increased age [32,34] and low body mass index (BMI) [34]. Of 27 cases where pain resulted from a motor vehicle accident, seven patients [26% (95% CI: 9–43%)] had positive responses to SIJ blocks [31]. Younger age correlated with a diagnosis of internal disc disruption, and that SIJ pain was more likely in older individuals without thigh pain [37]. Of 11 patients who had persistent pain following a discectomy, nine [82% (95% CI: 59–100%)] had positive responses to provocation discograms, and none had positive responses to SIJ blocks. [35]. Twenty-eight patients had undergone lumbar fusion, and 43% (95% CI 25–61%) of these had positive SIJ blocks [33]. Of patients who had undergone fusion to the sacrum, 10/17 [59% (95% CI: 36–82%)] had positive responses to SIJ blocks.

Sacroiliac joint injections were performed in three additional studies of patients who had undergone lumbar fusion. In the first of these studies, criteria of unilateral pain, pain compatible with a SIJ distribution, tenderness in the sacral sulcus, absence of referred pain below the knee, and no evidence of an obvious lumbar cause of pain were met in 45 of 61 patients [38]. Positive responses, defined as at least 75% relief of pain, were reported in 14/40 [35% (95% CI: 20–50%)] of the remaining patients. An increased uptake in the SIJ on bone scintigraphy had no diagnostic value, with a sensi-

tivity of 0.43, a specificity of 0.65, and a likelihood ratio of only 1.23.

A retrospective study evaluated patients who had undergone previous lumbar fusion [39]. A combination of contrast medium, local anesthetic, and steroid was injected, and degree of pain relief was assessed at 15–45 minutes after the procedure. Of 34 selected patients, 20 [59% (95% CI: 42–76%)] had at least 75% relief.

The value of radionuclide bone scanning has been assessed in two further studies. One included 50 patients, of which, 31 [62% (95% CI: 49–75%)] had positive responses to blocks, defined as at least 80% relief, and four patients, all of whom had positive responses to blocks, had positive bone scans [40]. Using a single diagnostic block with at least 80% relief as the criterion standard, the specificity of bone scans was 100% and the sensitivity was 13%. The injections contained steroid and 1% lidocaine, 1% lidocaine alone, or 2% lidocaine alone.

The patients in the second study underwent radionuclide scanning followed by intra-articular injections of local anesthetic [41]. Thirty-nine patients were selected and intra-articular access was not achieved in seven (18%). Of the 32 patients who received the intra-articular injection, 13 [41% (95% CI: 24–58%)] reported at least 75% relief from pain. Increased radionuclide uptake was observed in six of these patients, resulting in a poor sensitivity of only 46%. Increased uptake on the symptomatic side was observed in only one patient who had a negative response to local anesthetic. The specificity of the test was 90%, with a likelihood ratio of 4.6.

The location of the index pain and referred pain was assessed in three studies.

Patterns of pain referral were reported in a retrospective study of patients with lower back or buttock pain who had positive responses to at least three physical examination tests and at least 80% relief following a single fluoroscopically guided intra-articular injection of lidocaine into the SIJ [42]. Unilateral pain was reported in 64% of patients and 36% had bilateral pain; 94% of patients had buttock pain, 72% had lower lumbar pain; and pain was referred to the thigh in 48% of patients and to the groin in 14%.

One study evaluated the predictive utility of the pattern of LBP in detecting its source, and it was reported that 87% of 31 patients who had positive responses to SIJ blocks did not have midline pain [36].

Pain patterns were recorded prior to injections of local anesthetic and steroid into 32 SIJs in 28 patients in a further study [43]. The selected patients had experienced at least 80% relief from a previous injection into the joint capsule, pain in the SIJ region with or without referred pain, and reproduction of pain by Gaenslen's or

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Patrick's tests. In all cases pain over the SIJ was recorded: 22/32 (69%) had pain in the medial buttock region, 12/32 (38%) had pain in the trochanter and lateral thigh regions, 10/32 (31%) had pain in the posterior thigh region, and 3/32 (9%) had groin pain.

Three additional studies evaluated the usefulness of physical examination findings.

In one study, 85 subjects with suspected SIJ pain underwent 12 physical examination tests, followed immediately by a fluoroscopically guided SIJ injection with 0.2–0.5 mL of contrast medium and up to 2.0 mL of a combination of lidocaine and celestone soluspan [44]. An international multidisciplinary panel of experts ranked 20 tests and the 12 most reliable were selected by consensus. Positive responses, defined as 90–100% relief from pain, were assessed 20 minutes postinjection, and were identified in 45 patients, [53% (95% CI: 42–64%)]. Seven additional patients reported 51–89% relief. The presence of pain above L5 was associated with a negative response to the injection. No single clinical test or combination of tests had a likelihood ratio greater than 1.3.

In a cohort of 50 patients who had pain in the sacral sulcus, aggravation of pain with three physical maneuvers, and had failed a physiotherapy treatment regimen, 30 [60% (95% CI: 46–74%)] had at least 80% relief from a diagnostic block using either steroid and 1% lidocaine, 1% lidocaine alone, or 2% lidocaine alone [45]. As 40% of patients who met those criteria had negative responses to diagnostic blocks, the authors concluded that their results did not support the use of provocation SIJ maneuvers to confirm a diagnosis of intra-articular SIJ pain.

A prospective study sought to identify components of a physical examination that are associated with symptomatic lumbar discs, zygapophysial joints, and SIJs [46]. A total of 104 injections were performed on 81 patients. A pain generator was identified in 51 [63% (95% CI: 52–74%)]. At least 80% relief was required for a positive response. Positive responses were reported in 22/57 [39% (95% CI: 26–52%)] of SIJ injections. Clinical factors that were predictive of a positive response were unilateral pain and three or more positive pain provocation tests.

A retrospective study compared the effects of intra-articular injections in 40 patients to a modified technique of combined intra-articular and extra-articular injections in 80 patients [47]. Bupivacaine and methylprednisolone were injected in both groups, and 75% relief was reported in 43% (95% CI: 28–58%) of patients who had intra-articular injections and 63% (95% CI: 52–74%) who were injected with the modified technique.

In another study, 34 patients with suspected SIJ pain were injected with 1.5 mL of 2% lidocaine and 1 mL of a corticosteroid [48]. A positive block, defined as >79%

relief of index pain within the first 2 hours post-injection, was found in 32% (95% CI: 16–48%).

At Least 50% Relief from Local Anesthetic

In one study, 16 of 54 consecutive patients who had been referred for evaluation of disc and zygapophysial joint pain met the criteria for a positive "Fortin Finger Test" [49]. All had positive responses to provocation injections of contrast medium on the symptomatic side. The volume of injections ranged from 1.0 to 2.7 mL. Ten patients [63% (95% CI: 39–87%)] had at least 50% relief from a subsequent injection of bupivacaine and two of these, 13% (95% CI: 0–29%), had complete relief.

Relief from pain provocation in response to three physical exam maneuvers (flexion abduction external rotation, posterior shear, and resisted abduction) was examined in a randomized controlled trial [50]. Forty patients with suspected SIJ pain were selected on the basis of clinical history and pain reproduction in response to the three maneuvers and were injected with 0.5 mL of contrast medium and 4 mL of either 1% lidocaine or saline. The results may be limited by the large volume of injectate (4.5 mL) suggesting a low likelihood of target specificity.

In an audit of consecutive patients, 33/52 [63% (95% CI: 50–76%)] who underwent injections of lidocaine and triamcinolone had positive diagnostic responses, defined as 50% or greater relief of pain during the local anesthetic phase [51]. Fifty-six percent (95% CI: 43–69%) of patients experienced over 70% improvement and 31% (95% CI: 18–44%) of patients experienced 100% improvement.

A retrospective review evaluated the correlation between age, gender, and BMI as they relate to responses to local anesthetic blocks [52]. After undergoing local anesthetic blocks with lidocaine, patients with positive responses had injections of bupivacaine and one of two steroids. Of 158 patients, 91 [58% (95% CI: 50–66%)] had at least 70% relief from the first injection of lidocaine and 42 patients [27% (95% CI: 20–34%)] had relief from both injections.

A retrospective audit of all patients who had SIJ injections of local anesthetic and steroid with at least 2-year follow-up revealed 69 (45%) of 155 patients had prior lumbar surgery [53]. Thirty-five patients were nonresponders, defined as having had less than 50% relief during the local anesthetic phase or at least 50% relief but for less than 2 weeks. Estimates of relief were made qualitatively by patients.

A pragmatic trial was performed in 2014, to compare the outcomes from SIJ injections of bupivacaine and depo-methylprednisolone, lumbar sympathetic blocks,

and stellate ganglion blocks in sedated and nonsedated patients [54]. For 57 patients who underwent SIJ injections, the mean reductions in pain intensity, measured by the NRS, were 3.7 in the sedation group and 2.5 in the nonsedation group. At least 50% relief was reported in 70% (95% CI: 59–81%) of all patients who were sedated and in 54% (95% CI: 43–65%) of patients who were not sedated.

The Role of Provocation Examination Maneuvers

Patients were selected for SIJ injections primarily because of pain in the SIJ region, with or without tenderness. In the majority of studies, several provocation maneuvers were performed, the goal of these maneuvers being to assess whether or not the patient's accustomed pain was reproduced. The provocation tests used most often were Patrick's test, Gaenslen's test, Yeoman's test, the distraction test, the compression test, the sacral pressure test, and sacral thrust.

In some studies, a positive response to these tests, most commonly to either one or three maneuvers, was a criterion that determined whether or not injections were performed [20,23,28,43,45,54] and in some studies, provocation maneuvers were not performed [29,41,47,49,52].

In several studies provocation maneuvers were performed after patients had been selected for intervention, and these studies provided data about the utility of these tests. Two studies found that no single provocation test or combination of tests was a useful predictor of SIJ pain; seven tests and 12 tests were performed in these studies, respectively [19,44]. In one study, none of five provocation tests, or a specific combination of tests, were favorable but positive responses to three or more tests had a likelihood ratio of 4.02 [25]. Significant relationships between three or more provocation tests and a response to SIJ injection were reported in three further studies, with reported likelihood ratios of 1.9 and 4.29 [21,46,48].

When results from studies in which the criterion for a positive response was at least 75% were pooled, the proportion of patients who had positive responses to controlled local anesthetic blocks, and in whom a positive response to provocation examination maneuvers was a selection criterion, was 24% (95% CI: 18–30%) [20,23] and the proportion who had positive responses to controlled blocks when response to provocation maneuvers was not a selection criterion was 22% (95% CI: 14–30%) [19,21]. Pooled figures from studies in which blocks were not controlled reveals a trend toward a higher success rate when patients were selected if they had positive responses to at least three provocation maneuvers, with 46% (95% CI: 40–52%) of patients having at least 75% relief from pain [28,40], compared to 44% (95% CI: 37–51%) when provocation maneuvers were performed but were not a selection criterion [44,46,48] and 37% (95% CI: 28–46%) when patients

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were selected on the basis of location of pain without any provocation testing [29,41,47]. Though these trends favored selection of patients according to responses to at least three provocation examination maneuvers, the differences are not statistically significant.

Therapeutic Injections of Steroid

One study evaluated 22 patients with seronegative spondyloarthritis and pain attributed to the SIJ [55]. A total of 42 fluoroscopically guided SIJ injections using steroid without local anesthetic were performed. Odom's criteria was used as an outcome measure with 16 patients reporting 80–100% relief and three patients reporting 70–80% relief with a minimum duration of 1 month. The mean duration of improvement was 8.4 ± 4.5 months (range 1–15 months). The study was limited by the lack of validated outcome measures, the large volumes of injectate, and the lack of confirmatory signs and symptoms of SIJ pain.

An explanatory randomized-controlled trial compared fluoroscopically guided injections into the SIJ of steroid vs saline in patients with seronegative spondyloarthritides and radiologic evidence of sacroiliitis [56]. A total of 13 injections were performed in 10 patients: seven joints were injected with saline and six with steroid. One patient in the placebo group had at least 50% pain relief at 1 month [20% (95% CI: 0–55%)]. In the steroid group 100% of patients had at least 50% relief at 1 month. The outcomes were statistically significant, but the validity of the results is uncertain because none of the seven reported outcome measures were validated.

Liliang reported results of an aforementioned prospective observational study [23]. Of the 88 with a positive initial response, 20 patients did not report a recurrence of the SIJ pain after the injection. Of the 39 patients with a positive response to dual diagnostic blocks, 26 (67%) experienced more than a 50% reduction in pain for more than 6 weeks. If we assume the 20 patients whose pain resolved with the first injection have true SIJ arthropathy, the success rate of the injection may be as high as 78% (46/59). However, this study demonstrates the majority of patients with presumed SIJ pain will not respond to SIJ injections.

Another study assessed 22 fluoroscopically guided SIJ injections in 17 patients with ankylosing spondylitis and severe LBP, presumed to be sacroiliac arthropathy [57]. Fifteen of 17 [88% (95% CI: 73–100%)] patients reported "good" improvement within the first month follow-up and 13/17 [76% (95% CI: 56–96%)] decreased NSAID usage. No validated outcome measures were used and there were no data provided on more distant time frames or durations of relief.

Another observational study reported on 10 patients who underwent intra-articular injections of 6% phenol, following 2–4 weeks of pain relief from previous injections of bupivacaine and methylprednisolone [58].

Unfortunately, this study offers no useful outcome data for intra-articular corticosteroids, as the reported outcome measure of a short-term response to a steroid injection was also the inclusion criteria for this study.

A pragmatic trial compared outcomes from physiotherapy exercises, manual treatment, and one or two intra-articular SIJ injections of lidocaine and triamcinolone [59]. Local anesthetic blocks were not used for diagnosis. Success was defined as either complete relief at 6 or 12 weeks, or less pain at 12 weeks than baseline, and was claimed to have occurred in 72% (95% CI: 51–93%) of patients provided with manual therapy, in 20% (95% CI: 0–40%) among those receiving physiotherapy, and in 50% (95% CI: 27–73%) of patients provided with injections; however, data about the proportion of patients who had complete relief from pain were not provided. Mean reductions in pain intensity were less than the minimal clinically important change of 2.0 in all of the groups, at both 6 weeks and 12 weeks. Without diagnostic injections of local anesthetic, it is not known if these patients had SIJ pain.

A retrospective review included 31 patients with presumed SIJ pain, based on physical examination, who had not improved after at least 4 weeks of physical therapy [60]. Diagnostic, fluoroscopically guided SIJ injections with 2% lidocaine were performed on these patients. All patients had a positive diagnostic response, defined as >80% relief at the immediate postinjection interview. These patients received at least one fluoroscopically guided intra-articular therapeutic SIJ injection using a combination of 2.0 mL betamethasone sodium phosphate and acetate suspension, 6 mg/mL, and 0.5 mL 2% lidocaine hydrochloride. An average of 2.14 (range, 1–4) therapeutic SIJ injections was administered.

The mean VAS score at initial presentation was 74.6 points, which improved by 42.5 points at discharge [a 32.1-point improvement with a standard deviation (SD) of ± 26.0], and by 42.3 points (a 31.6-point improvement with a SD of ± 20.4) at follow-up. A significant reduction ($P > 0.0001$) in VAS score was noted from initial presentation to both the time of discharge and follow-up but this interval was not standardized. The initial mean Oswestry disability index (ODI) was 44.6 points, which improved by 10.9 points (SD ± 15.3) and was noted to be statistically significant.

A prospective observational study compared outcomes from injections of lidocaine and methylprednisolone between fusion and nonfusion patients [61]. Patients were selected on clinical and radiologic grounds, and on the basis of a response of at least $75\pm$ relief from a compression test following an injection, but the injectate is not described. However, with no record of pain relief from local anesthetic injections, no categorical data, and unusually long follow-up periods, this study has not provided convincing data about the effectiveness of intra-articular injections of steroid.

Patients in a pragmatic study published in 2014 were randomized to undergo intra-articular injections of contrast medium, lidocaine, and dexamethasone under either fluoroscopic guidance or ultrasound guidance [62]. Patients were selected according to history, positive findings on at least one of three provocation tests imaging findings, and at least 80% relief from a diagnostic injection. There were 55 patients in each group and outcomes were assessed at 2 weeks and 12 weeks. Only mean figures were provided and there were no significant differences between the two groups. In the fluoroscopy group, mean pain scores on the NRS decreased from 6.45 to 3.14 at 2 weeks (51.3% reduction) and 2.56 at 12 weeks (60.3% reduction). Radiographs were taken to check for accuracy of the injections, which were reported as 98.2% in the fluoroscopy group and 87.3% in the ultrasound group. Results of technically inaccurate injections were included in the outcome data limiting the ability to draw accurate conclusions.

One article compared patients' pain relief with contrast media flow during SIJ [63]. This study showed no differences in pain scores at 2 months between patients when the contrast medium reached the superior aspect of the joint or when there was poor cephalad spread of contrast medium. Using a generous definition of success of a mere 1.8-point reduction on a 10-point numeric pain scale, the authors reported 84% (95% CI: 74–94%) success at 2 weeks and 65% (95% CI: 52–78%) success at 8 weeks collectively.

Summary

Prevalence and Predictors of Response to Diagnostic SIJ Injections

Prevalence data have been summarized in Table 1 and Figure 1. When viewing the data as a whole, several trends emerge. First, utilizing dual controlled blocks significantly decreases the positive response rate. Studies utilizing single blocks report rates of 29–63%, while studies utilizing dual blocks report rates between 10% and 33% (with only one study showing higher rates at 45%). Additionally, increasing the percentage of pain relief required for a positive block also decreases the reported prevalence of SIJ pain. Differences mainly arose when relaxing criteria from >75% to >50% pain relief. The prevalence of SIJ pain appeared higher in studies in which both local anesthetic and steroid were injected.

The literature suggests the prevalence of SIJ pain is between 33% and 59% in those that have had a lumbar spine fusion depending on the exact criteria utilized for selection [24,33,38,39]. Multiple studies have shown increasing prevalence with increasing age [32,34,37], but there have been mixed results regarding the association of BMI and SIJ pain [34,64]. Several retrospective studies have also revealed increased prevalence in those with a history of trauma (most commonly motor

Table 1 Prevalence based on injections

| Percentage Relief | Percentage Positive | 95% CI | References |
|---|----------------------|------------|---|
| Selection based on controlled local anesthetic blocks | | | |
| At least 80% relief | 10% | 0–23% | Manchikanti [20] |
| At least 75% relief | 19% | 9–29% | Maigne [19] |
| At least 50% relief | 45% | 32–58% | Van Der Wurff [25] |
| Selection based on controlled injections of local anesthetic and steroid | | | |
| At least 80% relief | 33% | 20–46% | Laslett et al. [21,22] |
| At least 75% relief | 26% | 19–33% | Liliang et al. [23] |
| | 33% | 26–40% | Liliang et al. [24] |
| At least 50% relief | 27% | 20–34% | Irwin et al. [52] |
| Selection based on uncontrolled local anesthetic blocks | | | |
| At least 80% relief | 42% | 35–49% | Chou et al. [28] |
| | 32% | 16–48% | Stanford et al. [48] |
| At least 75% relief | 30% | 16–44% | Schwarzer et al. [29] |
| | 18% | 12–24% | DePalma et al. [36] |
| | 39% | 26–52% | Young et al. [46] |
| | 41% | 24–58% | Maigne et al. [41] |
| At least 50% relief | 62% | 38–86% | Fortin et al. [6] Fortin et al. [49] |
| Selection based on uncontrolled injections of local anesthetic and steroid | | | |
| At least 90% relief | 53% | 42–64% | Dreyfuss et al. [44] |
| At least 80% relief | 62% | 49–75% | Slipman et al. [40] |
| | 60% | 46–74% | Slipman et al. [45] |
| At least 75% relief | 42.5% | 27.5–57.5% | Borowsky et al. [47] |
| At least 50% relief | 70% with sedation | 59–81% | Cohen et al. [54] |
| | 54% without sedation | 43–65% | |
| | 63% | 50–76% | Chakraverty et al. [51] |

vehicle accidents), falls onto the buttock, lifting, or spontaneous onset [30,32].

SIJ injections are typically performed on those who have localized pain over the SIJ. Numerous studies suggest pain over the buttock alone has a very low positive predictive value for determining those that will respond to intra-articular injections.

Positive responders to injections can have somatic referred pain that radiates to the medial buttock and lower lumbar regions (69–72%), groin (9–14%), thigh (31–48%), and the greater trochanter (38%) [43].

Other diagnostic tools have also been compared to image-guided intra-articular injections, including physical examination and imaging. The literature has not demonstrated a single physical exam maneuver with a likelihood ratio greater than 1.3 for predicting a positive response to intra-articular anesthetic [19,29,44]. However, studies from the same group of authors [21,22,46] have reported that responses to at least three exam maneuvers (FABER, Thigh Thrust, Gaenslen’s, Distraction, Sacral Thrust, and Compression) were predictive of a positive response with a reported sensitivity of 78%. In several studies, patients were selected for investiga-

tion with local anesthetic injections if they responded to at least three [25] or four [24] provocation tests. Comparison with patients who did not respond to these tests was not made, but a significant percentage of patients who had positive responses to these maneuvers had negative responses to local anesthetic blocks. In patients without spondyloarthropathies, radiologic findings do not appear to correlate with responsiveness to diagnostic SIJ blocks.

Radionuclide Scanning

Three studies, including one of the studies in which patients underwent control blocks, consistently showed that bone scans have high specificity (65–100%) and poor sensitivity (13–46%) [22,38,40].

Effectiveness of Image-Guided Intra-Articular Corticosteroid Injection

Effectiveness data have been summarized in Table 2. The highest reported success rate from image-guided intra-articular SIJ injections was demonstrated in an explanatory randomized controlled trial (RCT) on 13 joints in patients with ankylosing spondyloarthritis [56] and in an observational study on 17 patients with

Table 2 Effectiveness of intra-articular SIJ injections

| Selection Criteria | Total n and Dose | Outcomes | Follow-up | References |
|---|--|--|--------------------------------------|---------------------|
| Explanatory RCT | | | | |
| Prospective double blind steroid vs saline with independent follow-up | n = 10 patients, 13 joints Injectate: 1.5 mL of cortivazol, equivalent to 62.5 mg prednisone | Mean Pain Steroid: 6.8–1.3 Saline: 7.0–5.2 NSAID Use Steroid: 50% decrease Saline: 14% decrease Duration of Relief Steroid: 5/6 with pain relief at 1 month 4/6 with pain relief at 3 and 6 months Saline: 1/7 with relief at 1 month | Primary at 1 month Up to 6 months | Maugars et al. [56] |
| Pragmatic RCT | | | | |
| Prospective with two arms, steroids and prolotherapy | n = 48 Steroid Group n = 25 Injectate: 2.5 total mL; 1 mL of triamcinolone acetate (40mg/mL) and 1.5 mL of levobupivacaine (0.125%) Prolotherapy Group n = 23 Injectate: 2.5 mL of 25% dextrose solution | 50% Improved at 6 Months Steroid Group: 27.2% (95% CI: 10–44%) Prolotherapy: 63.6% (95% CI: 44–84%) Cumulative Incidence of Sustained Pain Relief at 15 Months Steroid: 10.2% (95% CI: 0–22%) Prolotherapy: 58.7% (95% CI: 39–79.5%) | 6 months | Kim et al. [65] |

Table 2 *Continued*

| Selection Criteria | Total n and Dose | Outcomes | Follow-up | References |
|---|--|--|--------------------|---------------------|
| Observational studies | | | | |
| Selected based on controlled (dual) blocks | | | | |
| Retrospective | <p>≥80% pain relief from dual blocks. Initial screen anesthetic only followed by anesthetic and steroid for confirmation</p> <p>n = 54 Injectate: 2.0 mL of betamethasone sodium phosphate and acetate suspension (6mg/mL) and 0.5mL of 2% lidocaine hydrochloride</p> | <p>≥80% Pain Relief: 28% (95% CI: 16–40%)</p> | 2 weeks | Chou et al. [28] |
| Prospective | <p>≥75% pain relief from controlled blocks with anesthetic and steroid</p> <p>n = 58 Injectate: 1 mL of bupivacaine (0.5%) or lidocaine (2%), each mixed with 1 mL triamcinolone acetonide (40 mg/mL)</p> | <p>>50% Pain Relief: 67% (95% CI 52–82%)</p> | 6 weeks | Liliang et al. [23] |
| Retrospective | <p>≥70% pain relief with lidocaine only on initial injection, and confirmed by second injection with anesthetic and steroid.</p> <p>n = 42 Injectate: 2 mL of bupivacaine (0.25%) with either methylprednisolone (80 mg) or betamethasone sodium phosphate and acetate suspension (6 mg)</p> | <p>50% Pain Relief: 18/42 [43% (95% CI: 28–58%)]</p> | 1 month | Irwin et al. [52] |
| Selected based on uncontrolled (single) blocks | | | | |
| Retrospective | <p>≥80% pain relief from single anesthetic block</p> <p>n = 31 Injectate: 2.0 mL of betamethasone sodium phosphate and acetate suspension (6 mg/mL) and 0.5 mL of lidocaine hydrochloride (2%).</p> | <p>VAS Mean Pain ± SD: 32.1 ± 26</p> | Average 94.4 weeks | Slipman et al. [60] |

Table 2 *Continued*

| | Selection Criteria | Total n and Dose | Outcomes | Follow-up | References |
|---------------|---|--|----------|--|---|
| Prospective | ≥80% pain relief with dual diagnostic blocks | n = 16 Injectates: First block – lidocaine “less than 1.5 cc of lidocaine” Second block–bupivacaine | | “Lasting Relief”: 3/16 [19% (95% CI: 0–38%)] | Laslett et al. [21] (<i>Subset of Data</i>) |
| Prospective | >80% pain relief with diagnostic injection | n = 110 1 mL of 0.5% lidocaine and dexamethasone, 10 mg | | Accuracy: Ultrasound guidance: 87.3% Fluoroscopic guidance: 98.2% Mean Pain (NRS): 6.45 to 3.14 (NRS) at 2 weeks (51.3% reduction) 2.56 at 12 weeks (60.3% reduction) | Jee et al. [62] |
| Retrospective | >75% pain relief from single block with anesthetic and steroid | n = 34 Injectate: “1–3 mL of a solution of nonionic contrast, local anesthetic, and a long-acting glucocortico-steroid” | | “Relief” >14 days: 11/34 [32% (95% CI: 16–48%)] No validated outcome measures | Katz et al. [39] |
| Prospective | ≥75% pain relief from single block with anesthetic and steroid | n = 88 Injectate: 1 mL, bupivacaine (0.5%) or lidocaine (2%), each mixed with 1 mL triamcinolone acetonide (40 mg/mL) | | % Reporting enough relief to not need a second injection: 20/88 [23% (95% CI: 14–32%)] | Liliang et al. [23] (<i>Subset of data</i>) |
| Retrospective | ≥70% pain relief with lidocaine only | n = 67 Injectate: 2 mL of lidocaine (2%) | | >70% Pain Relief for 1 Month: 7/67 [10% (95% CI: 3–17%)] Note no steroid was given in this group, these results are after anesthetic only | Irwin et al. [52] (<i>Subset of Data</i>) |
| Retrospective | ≥50% pain relief after injection of anesthetic and corticosteroid | n = 33 Injectate: <3 mL of 2% lignocaine and triamcinolone | | Pain Relief Only for Duration of Anesthetic: N = 10/33 Pain Relief for 1 day-4 Weeks: N = 7/33 Pain Relief for 1-3 Months: N = 3/33 Pain Relief 3-6 months: N = 1/33 Pain Relief >6 months: N = 11 ODI collected but not reported | Chakraverty et al. [51] |

Table 2 *Continued*

| | Selection Criteria | Total n and Dose | Outcomes | Follow-up | References | |
|-------------------------------|---|--|----------|--|-------------------------------------|---|
| Not Selected on Blocks | | | | | | |
| Prospective | Sacroiliitis with a sero-negative spondylo-arthropathy | n = 42 joints 1.5 mL of Cortivazol equivalent to 62.5 mg prednisone | | % Improvement maintained for at least 1 month 100% improvement 11/42 (26.2%) 80–90% improvement 17/42 (40.5%) 70–80% improvement 6/42 (14.3%) 50–70% improvement 2/42 (4.8%) | Mean follow-up 15.4 ± 6.6 months | Maugars et al. [55] |
| Prospective | Ankylosing spondylitis and suspected SIJ pain | n = 17 Injectate: Diprosan, 1 mL; 14 mg, betamethasone | | “Good” Improvement: 88% (95% CI: 73–100%) Decrease NSAID Usage: 13/17 [76% (95% CI: 56–96%) “Lasting Relief”: 3/48 [6.3% (95%CI: 0–13%)] | 1 month | Karabacakoglu et al. [57] |
| Prospective | History suggestive | n = 48 Injectate: “less than 1.5 cc of lidocaine” | | <50% relief during anesthetic phase or at least 50% relief for less than 2 weeks: 35/155 [23% (95% CI: 16–30%) <i>Patients who had > 1 injection had an average of 9.3 months relief per injection (range: 1–58 months)</i> | “lasting relief” | Laslett et al. [21] (<i>Subset of Data</i>) |
| Retrospective | History suggestive | n = 155 155 patients received SIJ of local anesthetic and steroid in a 2-year period. | | <i>Patients who had > 1 injection had an average of 9.3 months relief per injection (range: 1–58 months)</i> Either Complete Relief at 6 or 12 Weeks, or Less Pain at 12 Weeks than Baseline: 50% (95% CI: 27–73%) <i>Data not provided about proportion of patients with complete relief</i> Mean reductions in pain intensity were less than the minimal clinically important change of 2/10 | 2 years | Hawkins et al. [53] |
| Prospective | Pain in SIJ region and 3 or more positive provocation tests | n = 18 30 mg of lidocaine and 20 mg kenacort. <i>Total amount given varied from 0.6 to 2.0 mL (mean 1.1 mL).</i> | | | 6 and 12 weeks | Visser et al. [59] |

Table 2 Continued

| | Selection Criteria | Total n and Dose | Outcomes | Follow-up | References |
|-------------|--|--|----------|---|--|
| Prospective | Tenderness overlying the SIJ and positive responses to provocation tests | n = 57 3.5 mL of 2 mL of bupivacaine 0.5% and 1.5 mL of 40mg/mL depomethyl-prednisolone | | Mean pain reduction on NRS at 6 hours: 3.7 in sedation group 2.5 in nonsedation Percentage of patients reporting at least 50% pain relief at 6 hours: Sedation Group: 70% (95% CI: 59–81%) Nonsedation Group: 54% (95% CI: 43–65%) <i>1 month data not presented for subgroup of patients receiving SIJ injections</i> | 6 hours and 1 month Cohen et al. [54] |
| Prospective | Clinical exam and radiologic findings, and $\geq 75\%$ pain relief from compression test following SIJ injection | n = 72 1 cc methylpred-nisolone and 1 cc of lidocaine HCL | | Mean pain with activity: nonfusion patients: 9.08 \pm 0.98 to 2.78 \pm 3.46 patients with fusion: 8.30 \pm 1.59 to 3.11 \pm 1.77 Multiple injections: nonfusion patients: 9/50 (18%), mean timing 11.1 months fusion patients: 12/22 (54.5%), mean timing of 5.91 months | Average 17.7 months (range 6–30 months) Büker et al. [61] |

Fluoroscopically Guided Sacroiliac Joint Injections

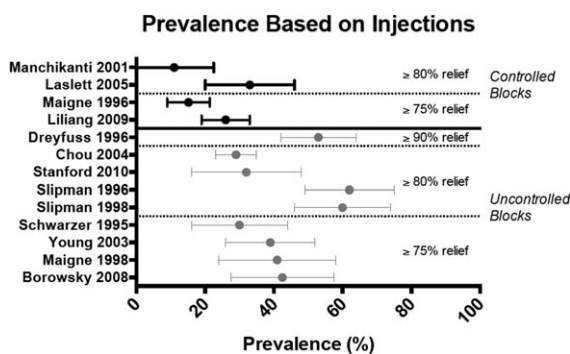


Figure 1 Prevalence based on injections.

ankylosing spondylitis [57]. Both of these studies were small and did not utilize diagnostic blocks to select patients, but they did show statistically and clinically significant improvements with the injection of a corticosteroid. The Maugars study showed decreased mean pain scores, decreased NSAID usage, and longer duration of relief with steroid over saline [56]. The Karabacakoglu study also showed decreased NSAID usage after an injection [57].

In patients with suspected SIJ pain and no spondyloarthropathy, the literature must be viewed based on the rigor of the diagnosis. No studies have been done that have selected patients who had complete relief after receiving dual comparative intra-articular blocks with local anesthetic only. Three studies, which used controlled blocks of local anesthetic only, had varied criteria for positive responses of at least 80% relief [20], 75% [19], and 50% [26]; and one study used controlled blocks of local anesthetic and steroid [24]. A few studies have been done that selected patients for therapeutic injections after dual blocks with anesthetic and corticosteroid. Two retrospective and one prospective observational studies required a positive response of at least 70% pain relief from dual intra-articular blocks with anesthetic and corticosteroid for inclusion, with a total of 160 combined subjects [21,28,52]. These data showed 43–67% of subjects had at least 50% pain relief for 4–6 weeks, and 28% reported 80% pain relief for 2 weeks.

Multiple other studies only required a positive response after a single block, with a total of 301 combined patients. Combining these studies was challenging due to the lack of categorical data and the variable and sometimes nonvalidated outcome measures that were utilized. Patients diagnosed with SIJ pain based on the results of only a single diagnostic block showed greater variability in their responses than those diagnosed by dual controlled blocks. In a subset of patients from the study by Liliang et al. only 23% (95% CI: 14–32%) of patients that had positive response to a single block did not require a second injection due to adequate pain relief [23]. Irwin found that 10% of patients that received a local anesthetic injection had >70% pain relief at

1 month [52]. Kim et al. performed a pragmatic RCT in 48 patients that demonstrated 27% (95% CI: 10–44%) of subjects who underwent a steroid SIJ injection had 50% pain relief for 6 months, and 64% (95% CI: 44–84%) of those that received prolotherapy had 50% pain relief at 6 months [65]. This study is somewhat confounded by the fact that subjects received varying numbers of injections that were not reported in a categorical fashion to facilitate further comparisons.

Most studies utilizing single blocks also reported on the duration of pain relief. The average duration of relief was found to be 76–94.4 days [60]. When subjects were selected based on history and physical exam findings, three of the 16 [19% (95% CI: 0–38%)] patients with a positive diagnostic block had lasting relief. Katz reported that only 32% (95% CI: 16–48%) of 34 subjects had relief for more than 14 days [39]. Chakraverty noted that 45% (95% CI: 28–62%) had relief lasting at least 1 month [51]. Irwin found only 10% (95% CI 3–17%) of 67 patients had relief for 1 month [52].

Complications Following Intra-Articular Injections

Plastaras et al. studied complications of diagnostic SIJ procedures [66]. There were no adverse effects secondary to SIJ injections, but 5/191 [3% (95% CI: 0–6%)] patients experienced immediate transient reactions and 32/132 [24% (95% CI: 17–31%)] had a delayed adverse event, the most common being increased pain. Kennedy et al. found 2.5% of 525 SIJ injections had a vasovagal reaction [67]. There is one case report of pyogenic sacroiliitis following an injection [68] and one of reactivation of herpes simplex [69]. However, with a common condition such as herpes simplex, it is unclear whether the event was causally related or simply correlated.

Temporary sciatic palsy was reported in two studies, with 3/67 cases in one [19] and 5/60 in the other [25]. Several studies reported procedures that were technically unsuccessful with rates of 10% (95% CI: 3–17%) [19], 11% (95% CI: 2–20%) [38], and 18% (95% CI: 6–30%) [22].

Discussion

This review was undertaken as one contribution to a multisociety Appropriate Use Criteria Task Force project convened by the International Spine Intervention Society. Its aim was limited to describing the scientific evidence relating to: 1) the validity of fluoroscopically guided diagnostic SIJ injections to diagnose SIJ pain and predict a subsequent therapeutic response, and 2) the effectiveness of fluoroscopically guided therapeutic SIJ injections for the treatment of SIJ pain, 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 SIJ.

In addition to evaluating the quality of evidence on a given topic, the Grades of Recommendation, Assessment,

Development, and Evaluation (GRADE) system allows for assessment of the strength of recommendations 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 [70]. The authors of this article have deliberately refrained from addressing strength of recommendations for use of diagnostic and therapeutic SIJ injections 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.

There are several key considerations that must be taken into consideration when determining the utility of image-guided SIJ injections. First, target-specificity is an essential criterion in assessing the validity of a local anesthetic block. If a block is not target-specific it cannot be valid, because any diagnostic inferences cannot be legitimately attributed to anesthetization of the purported target [10]. Positive target-specificity means that the block succeeds in anesthetizing the target structure. Negative target-specificity means that the block does not anesthetize other structures that might feasibly be a rival source of pain. Negative target-specificity is as important as positive target-specificity because, if a positive response is due to rival sources of pain being anesthetized but not recognized, the diagnostic inferences drawn will be wrong. Also concerning for diagnostic SIJ injections, false-positive rates of at least 19% [28], 20% [19,22], and 22% [20] have been calculated.

Target-specificity is tested in SIJ blocks with an injection of a small volume of contrast medium, performed under fluoroscopic guidance. Features that confirm target specificity are: an arthrogram, demonstrating linear streaks of contrast medium between the joint margins; absence of escape of contrast medium into or onto structures surrounding the joint including ventral capsule tears; and confirmation that intravascular injection has not occurred. Several studies noted sciatic nerve palsy as a complication from the injection. This is likely due to anesthetic contacting the sciatic nerve via an anterior capsular tear. This finding does call into question the specificity of these cohorts and the injection. Additionally, of paramount importance to accuracy is the ability to recognize when the procedure is technically impossible. Only a few studies reported the inability to access the joint; with rates reported between 4% and 20% of attempted injections being unsuccessful [19,21,22]. It is not clear how this rate varies among practitioners, as this data is not frequently reported. Based on studies of other interventional procedures, training may have an influence on procedural awareness and accuracy [71,72], but this has not been studied in the SIJ.

There are no studies that provide information about the prevalence of SIJ pain in the general population. Patients studied were referred to specialist units, often specifically for invasive interventions, and the data pro-

vided in these studies may not apply to all back pain patients. In the majority of studies, injections were performed only on patients in whom SIJ pain was suspected, on the basis of the location of pain, with or without aggravation of pain in response to provocation physical examination tests. Also, the majority of the literature reporting prevalence data utilized diagnostic injections combining anesthetic and corticosteroid. Given the joint volume is only 1–2 mL, a mixed injection or local anesthetic and corticosteroid may not fully anesthetize the joint, and, thus, the reported prevalence data could be the result of an abnormally high false-negative rate.

Theoretically patients who undergo SIJ injections with local anesthetic and steroid should have a biphasic response: immediate and delayed. As some studies reported on the local anesthetic effects of these injections, those data were included in the diagnostic section of this article. When local anesthetic alone is injected, 87/246 [35% (95% CI: 29–41%)] patients had at least 75% relief. When local anesthetic and steroid were injected, 339/685 [49% (95% CI: 47–51%)] patients had at least 75% relief. As the CIs do not overlap, the addition of steroid increased the rate of positive responses to SIJ injections. The reasons for this increase are unclear.

The effectiveness data were evaluated in accordance with the GRADE system of rating quality of evidence [70]. The data for pain relief were evaluated at 1 month as there are no categorical data with a longer follow-up period. For therapeutic SIJ injections, there are two randomized controlled trials that provide categorical data for at least 1 month [56,65]. Mangers et al. [56] provide an explanatory study that suggests that therapeutic steroid SIJ injections provide greater relief than placebo for patients with spondyloarthropathy and radiologic evidence of sacroiliitis. While statistically significant changes were clearly observed for one outcome measure, no differences were found in the other six reported outcomes. Also none of the seven reported outcome measures were validated. The other published study by Kim et al. is pragmatic and offers outcome data at six months [65]. Unfortunately, the treatment groups underwent different numbers of injections and had varying durations of follow-up, thus, limiting the ability to draw conclusions. As the body of evidence demonstrating categorical pain relief at 1 month for therapeutic SIJ steroid injections comes from two randomized controlled studies, the body of evidence is potentially high quality in accordance with GRADE. However, the quality of evidence is downgraded to moderate due to the noted limitations of both studies. Data from the numerous observational studies are not strong enough to justify any upgrade. Further studies could change the overall estimate of the quality of literature for therapeutic SIJ injections.

To apply GRADE to diagnostic tests, consideration is given to what degree the use of the test results in improvement in the outcomes of interest. In this case,

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does a positive diagnostic block predict a positive response to an intra-articular corticosteroid injection? Using GRADE to assess the quality of the available literature on diagnostic SIJ injections proved far more challenging than its application to the literature on therapeutic injections, for several reasons. For the majority of studies in which corticosteroid was injected, patients were selected for treatment on clinical grounds. There were no randomized controlled trials in which the therapeutic outcomes of corticosteroid injections were assessed based on different diagnostic tests such as physical examination or anesthetic block. In some studies, repeat injections of corticosteroid and local anesthetic were performed if an initial injection of the same combination had provided relief. As these studies utilized combinations of medications, the validity of the anesthetic block is questioned. In the four studies that utilized diagnostic blocks prior to injection of corticosteroid and anesthetic, the validity scores of the initial diagnostic blocks were low [28,52,60,65]. These studies had varying criteria for defining a positive block ranging from 50 to 80% pain reduction. Two studies that regarded 80% relief from pain as a positive response either provided no categorical data about the outcome of the steroid injection or provided physical therapy programs in conjunction with the injections [60,62]. Only one study reported outcomes from steroid injections, and the follow-up time frame was only 2 weeks [28]. Therefore, diagnostic blocks cannot currently be assessed according to GRADE.

Instead, we used the “Bogduk Validity Score,” a metric suggested in a recent philosophical essay on the validity of diagnostic blocks [10]. This score stipulates that target specificity and duration are essential criteria, without which a block cannot be valid. Scores for diagnostic blocks, which satisfy the essential criteria, are based on effect, consistency, replication, and the use of controls. Points can be added for plausibility, experiment, and replication. Based on these criteria, this literature for diagnostic SIJ injections merits a score of 16/24 on this scale, with points awarded as follows: effect [2], consistency [4], use of comparative blocks [2], with concordant responses [4], plausibility [1], experiment [1], and replication [2]. A higher score is precluded by the absence of studies in which placebo controls were used, with complete relief from pain reported, and in which the selection of local anesthetic for comparative blocks was double-blind. These low scores are a reflection of this literature, not the diagnostic validity of intra-articular local anesthetic only SIJ injections.

The majority of diagnostic literature, thus, far has focused on the prevalence of those that respond to intra-articular anesthetic blocks, and the ability of the physical examination to predict a positive response to a block. The literature has not fully evaluated the ability of a diagnostic block to predict a response to a given treatment. Collectively it does appear that there is a trend toward greater relief in those selected by dual blocks as opposed to those only receiving single blocks.

However, this literature has caveats that make interpretation difficult, including the use of both anesthetic and corticosteroids in blocks and subjects receiving multiple injections with corticosteroid.

Conclusions

When confirmed by comparative anesthetic blocks with a high degree of pain relief, the prevalence of SIJ pain is likely between 20% and 30% among patients that have suspected SIJ pain based on history and physical examination. No single physical exam maneuver is predictive of those that will respond to a diagnostic injection, but when at least three physical exam findings are present the sensitivity and specificity increases when compared with single diagnostic injections. Nevertheless, the diagnostic confidence based on this criterion is 55% secondary to the low prevalence of SIJ pain. It is also not clear if image-guided intra-articular diagnostic injections of a local anesthetic predict a positive response to a therapeutic agent. Despite being limited significantly by less rigorous inclusion criteria, the overall quality of evidence for therapeutic SIJ injections is moderate.

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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

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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% (CI₉₅ 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% (CI₉₅ 69–100%) reported >50% relief of pain, and two of the nine or 22% (CI₉₅ 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 = sacroiliac joint block; SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

nine of 14 patients or 64% (CI₉₅ 39–89%) had >50% decrease in visual integer pain score and 36% (CI₉₅ 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% (CI₉₅ 41–71%) reported at least 50% pain relief, and 10 or 23% (CI₉₅ 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% (CI₉₅ 54–96%) reported having had at least 50% relief from pain for 2 months, and 7 or 44% (CI₉₅ 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% (CI₉₅ 29–67%) of patients reported at least 50% pain reduction

at follow-up 3–4 months after treatment, and three or 11% (CI₉₅ 0–23%) had complete pain relief [26]. In the second, 12 of 15 patients or 80% (CI₉₅ 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% (CI₉₅ 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% (CI₉₅ 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% (CI₉₅ 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 $\geq 75\%$ Relief after a Single SIJB

| Group | RF Treatment | Follow-Up (Months) | Pain | Relieved $\geq 50\%$ (%) |
|-----------------------------------|--------------|--------------------|-------|------------------------------|
| Active group <i>n</i> = 14 | Cooled | 1 | 11/14 | 79 (CI ₉₅ 58–100) |
| | 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 <i>n</i> = 14 | Sham | 1 | 2/14 | 14 (CI ₉₅ 0–32) |
| | Sham | 3 | 0/14 | 0 |
| | Sham | 6 | 0/14 | 0 |
| Cross-over group <i>n</i> = 11 | Unipolar | 1 | 7/11 | 64 (CI ₉₅ 36–92) |
| | 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 $\geq 75\%$ Relief after Each of Two Sets of Single-Depth SLBBs

| Group | RF Treatment | Follow-Up (Months) | Pain | Relieved $\geq 50\%$ (%) |
|-----------------------------------|--------------|--------------------|-------|-----------------------------|
| Active group <i>n</i> = 34 | Cooled | 3 | 16/34 | 47 (CI ₉₅ 30–64) |
| | Cooled | 6 | 13/34 | 38 (CI ₉₅ 22–54) |
| | Cooled | 9 | 20/34 | 59 (CI ₉₅ 42–76) |
| Control group <i>n</i> = 17 | Sham | 3 | 2/17 | 12 (CI ₉₅ 0–27) |
| | Sham | 6 | 2/17 | 12 (CI ₉₅ 0–27) |
| Cross-over group <i>n</i> = 16 | Cooled | 3 | 7/16 | 44 (CI ₉₅ 20–68) |
| | 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 multi-site, 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 multi-site, 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

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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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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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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 | No provocation testing performed | No apparent inciting event | 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? |
| Normal imaging of the lumbar spine and pelvis | Provocation tests, negative | History of pelvic trauma | |
| Normal imaging of the lumbar spine, but degenerative SIJ findings on pelvic imaging | 1–2 provocation tests positive | Spondyloarthritis | |
| Degenerative changes in the lumbar spine and normal findings on pelvic imaging | 3 or more provocation tests positive | History of fusion through L5-S1 | |
| Degenerative changes in both the lumbar spine and SIJ | No diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on pelvic imaging | Negative diagnostic spine injection(s) | | |
| Normal imaging of the pelvis and abnormal findings on lumbar spine imaging | | | |
| Abnormal findings on imaging of both the lumbar spine and pelvis | | | |

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 | No provocation testing performed | No apparent inciting event | 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? |
| Normal imaging of the lumbar spine and pelvis | Provocation tests negative | History of pelvic trauma | |
| Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging | 1–2 provocation tests positive | Spondyloarthritis | |
| Degenerative changes in the lumbar spine and normal findings on pelvic imaging | 3 or more provocation tests positive | History of fusion through L5-S1 | |
| Degenerative changes in both the lumbar spine and SIJ | No diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on pelvic imaging | Negative diagnostic spine injection(s) | | |
| Normal imaging of the pelvis and abnormal findings on lumbar spine imaging | | | |
| Abnormal findings on imaging of both the lumbar spine and pelvis | | | |

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 | No provocation testing of SIJ performed | No apparent inciting event | 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? |
| Normal imaging of the lumbar spine and pelvis | Provocation tests of SIJ negative | History of pelvic trauma | |
| Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging | 1–2 provocation tests of SIJ positive | Spondyloarthritis | |
| Degenerative changes in the lumbar spine and normal findings on pelvic imaging | 3 or more provocation tests of SIJ positive | History of fusion through L5-S1 | |
| Degenerative changes in both the lumbar spine and SIJ on imaging | No diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on pelvic imaging | Negative diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on lumbar spine imaging | No provocation testing of hip performed | | |
| Abnormal findings on imaging of both the lumbar spine and pelvis | Provocation tests of hip negative | | |
| Abnormal findings on hip imaging | Provocation tests of hip positive | | |
| | No diagnostic hip injection(s) | | |
| | Negative diagnostic hip injection(s) | | |

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 | No provocation testing of SIJ performed | No apparent inciting event | 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? |
| Normal imaging of the lumbar spine and pelvis | Provocation tests of SIJ negative | History of pelvic trauma | |
| Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging | 1–2 provocation tests of SIJ positive | Spondyloarthritis | |
| Degenerative changes in the lumbar spine and normal findings on pelvic imaging | 3 or more provocation tests of SIJ positive | History of fusion through L5-S1 | |
| Degenerative changes in both the lumbar spine and SIJ on imaging | No diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on pelvic imaging | Negative diagnostic spine injection(s) | | |
| Normal imaging of the lumbar spine and abnormal findings on lumbar spine imaging | | | |
| Abnormal findings on imaging of both the lumbar spine and pelvis | | | |

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 | |
| 1–2 provocation tests of SIJ positive | Intra-articular SIJ injection of local anesthetic without steroid? |
| 3 or more provocation tests of SIJ positive | |
| No laboratory data | Intra-articular SIJ injection of steroid alone? |
| 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 | |
| Antiplatelet agents other than single-dose daily aspirin | Intra-articular SIJ injection of steroid alone? |
| Anticoagulation medication other than antiplatelet agents | Lateral branch blocks? |
| Anticoagulation and antiplatelet agents | Lateral branch radiofrequency neurotomy? |

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 | |
| ≥4 out of 10, but function not limited | 1–2 months | At least 3 months | Intra-articular SIJ injection of local anesthetic without steroid? |
| ≥4 out of 10, and functional limitations | 2–3 months | | |
| | Longer than 3 months | | Intra-articular SIJ injection of steroid alone? |

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 | Procedures |
|------------------|---|
| Degree of Relief | |
| <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? Intra-articular SIJ injection of local anesthetic without steroid? Intra-articular SIJ injection of steroid alone? Lateral branch blocks? |
| | ≥50% | | ≥50% | |
| | ≥75% | | ≥75% | |
| | 100% | | 100% | |
| Local anesthetic with steroid | <50% | Local anesthetic with steroid | <50% | 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? Lateral branch blocks? |
| | ≥50% | | ≥50% | |
| | ≥75% | | ≥75% | |
| | 100% | | 100% | |
| Local anesthetic | <50% | Local anesthetic | None | 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? Lateral branch blocks? |
| | ≥50% | | None | |
| | ≥75% | | None | |
| | 100% | | None | |
| Local anesthetic with steroid | <50% | Local anesthetic with steroid | None | 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? Lateral branch blocks? |
| | ≥50% | | None | |
| | ≥75% | | None | |
| | 100% | | None | |

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? Intra-articular SIJ injection of steroid alone? |
| Second or subsequent therapeutic injection | ≥50% | 2–4 weeks | |
| | ≥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 | | | | Duration of Symptoms | Procedure |
|------------------------|--------|-------------------------|--------|----------------------|--|
| First Diagnostic Block | | Second Diagnostic Block | | | |
| Site | Relief | Site | Relief | | |
| None | | None | | Less than 2 weeks | Lateral branch radiofrequency neurotomy? |
| Sacroiliac joint | <50% | Sacroiliac joint | <50% | 2–4 weeks | |
| Lateral branches | ≥50% | Lateral branches | ≥50% | 1–2 months | |
| | ≥75% | | ≥75% | 2–3 months | |
| | 100% | | 100% | More than 3 months | |

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 | | Duration of Relief | Procedure |
|-----------------|--|--------------------|--|
| Previous 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

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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 osteoarthritis (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).




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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 | <p><i>This test applies tensile force on the anterior aspect of the SI joint.</i></p> <p>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.</p> <p>The pelvis is stabilized at the opposite ASIS with the hand of the examiner.</p> |  |
| Thigh Thrust | <p><i>This test applies anteroposterior shear stress on the SI joint.</i></p> <p>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.</p> <p>The pelvis is stabilized at the sacrum or at the opposite ASIS with the hand of the examiner.</p> |  |
| Gaenslen's Test | <p><i>This test applies torsional stress on the SI joints.</i></p> <p>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.</p> |  |

ASIS = anterior superior iliac spine; SI = sacroiliac

| Test | Description | Photo |
|---------------|--|--|
| Distraction | <p><i>This applies tensile forces on the anterior aspect of the joint.</i></p> <p>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.</p> <p>A slow and steadily increasing pressure is placed through the arms and maintained.</p> |  |
| Compression | <p><i>This applies lateral compression force across the SI joint.</i></p> <p>The patient is placed in a side-lying position, facing away from the examiner, with a pillow between the knees.</p> <p>The examiner places a downward pressure through the lateral aspect of the patient's top side ASIS and pelvis, anterior to the greater trochanter.</p> |  |
| Sacral Thrust | <p><i>This test applies anteroposterior shear stress on the SI joint.</i></p> <p>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.</p> |  |

ASIS = anterior superior iliac spine; SI = sacroiliac

Hip Provocation Tests (Physical Exam Findings)

| Test | Description | Photo |
|---------------------------|---|--|
| Log Roll | <p><i>This test moves the articular surface of the femoral head in relation to the acetabulum without stressing extra-articular structures.</i></p> <p>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.</p> |  |
| Anterior Impingement Test | <p><i>This test places the femoral head in a flexed, adducted, and internally rotated position relative to the acetabulum.</i></p> <p>The patient lies supine. The examiner passively flexes hip and knee to 90 degrees, then internally rotates and adducts the hip 10 degrees.</p> |  |
| FABER/ Patrick's Test | <p><i>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.</i></p> <p>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.</p> |  |

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 diarthrodial 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.

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 $\geq 50\%$ 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 specifically¹⁹ 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 1Success rates for explanatory study by Patel et al^{9,33} and Cohen et al¹⁷ with >50% relief of index pain

| Treatment | >50% Pain Response* | | |
|-----------------------------|-----------------------------|-------------------------------|-----------------------------|
| | 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 al¹⁶ and Juch et al¹⁰ 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 | 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 = 32-44%) 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 a 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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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 PSN 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 perforaminal 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 perforaminal 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 $\geq 50\%$ 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 $\geq 50\%$ 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 perforaminal SLBRFA demonstrated success rates favoring the multi-electrode probe (71%) over perforaminal 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 $\geq 50\%$ 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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