



December 4, 2018

United Healthcare
Medical Policy Department
9500 Bren Road East
Minnetonka, MN 55343

via Email: mpq@uhc.com

Re: Ablative Treatment for Spinal Pain, Policy Number 2018T0107T

To Whom It May Concern:

The Spine Intervention Society, a multi-specialty association of over 2,800 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on your policy *Ablative Treatment for Spinal Pain, Policy Number 2018T0107T*.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has 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 so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

Third Occipital Nerve (C2-3) Denervation or Radiofrequency Neurotomy

The policy specifically excludes ablative procedures, including third occipital nerve (C2-3) denervation or radiofrequency (RF) neurotomy, for the treatment of chronic headaches and occipital neuralgia, suggesting that there is insufficient evidence to support its use. We are concerned that this is not consistent with the evidence in the literature and recommend coverage. Third occipital headache, its diagnosis by controlled blocks, and its treatment by RF neurotomy are recognized in prominent journals such as *Neurology* and the premier textbook on headache.^{1,2} For patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using appropriate techniques, third occipital nerve RF neurotomy is a proven, effective procedure.

In patients with chronic neck pain, the representative prevalence of cervical zygapophysial joint pain is in the order of 60% in patients.³⁻⁷ This makes it the single most common basis for chronic neck pain, and the only condition that can be diagnosed using validated diagnostic tests. No other causes of neck pain have diagnostic tests that

have been validated, and there has been no other cause in which the prevalence has been determined. In patients with positive responses to controlled, medial branch blocks, the segments most commonly positive are C2-3 and C5-6 followed by C6-7.⁷

In 1994, a substantive study using controlled diagnostic blocks of the third occipital nerve, which is the innervation to the C2-3 zygapophysial joint⁸, reported their yield in patients with headache after whiplash.⁹ It reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint.

It should be apparent that the C2-3 zygapophysial joint is a substantial pain generator not only in those with neck pain but in those with cervicogenic headache as well.¹⁰ If non-invasive conservative care fails to provide adequate pain relief for those with pain originating from this articulation, then C2-3 zygapophysial joint denervation via third occipital nerve thermal RF neurotomy should remain a viable option for this substantial subset of patients rather than relegating these patients to continued suffering or reliance on analgesics.

It appears that the primary justification for classifying C2-3 zygapophysial joint denervation as a not covered procedure, as opposed to the cervical zygapophysial joints at levels below C2-3, is the absence of a randomized controlled trial addressing this specific joint. There has been a seminal RCT on cervical medial branch neurotomy that demonstrates that the positive outcome of the procedure is clearly not due to placebo effects.¹¹ This study did not access the C2-3 level due to documented technical limitations of RF neurotomy of this level (at the time of the study) attributable to anatomic variation of its nerve supply (third occipital nerve).¹² More recently, following the Lord RCT, the technical limitations of the RF neurotomy technique have been addressed, which compensates for the unique anatomy of the third occipital nerve.¹³

Prospective observational evidence outside of RCTs can demonstrate the effectiveness of a procedure. In fact, when the outcomes of well-performed prospective trials demonstrate dramatic and sustainable results that are reproducible across studies, one could argue that the need to demonstrate that the effects of the procedure are not due to placebo effects alone are seriously minimized. This is more so the case when the procedure itself is in the same region of the spine for essentially the same anatomical condition (zygapophysial joint pain) and when the index procedure has already been shown to be effective in an RCT, for which the results cannot be attributed to a placebo effect.¹¹ This is indeed the case for C2-3 zygapophysial joint denervation, as compared to other cervical zygapophysial joints.¹³

Since the third occipital nerve RF neurotomy technique has been appropriately modified following the seminal Lord RCT, three studies evaluating the effectiveness of third occipital nerve neurotomy have been published.¹³⁻¹⁵ In a prospective trial, Govind specifically investigated the efficacy of radiofrequency neurotomy of the third occipital nerve for the treatment of headache via a modified technique.¹³ Modifications to the technique used included: using a large gauge electrode; holding the electrode firmly in

place throughout the period of coagulation; and placing consecutive, parallel lesions no further than one electrode-width apart. As a result of these modifications, previous results of third occipital neurotomy were reversed. Instead of four out of 10 patients obtaining relief,¹² **86% of 49 patients obtained complete relief of pain. At the time of publication, the median duration of relief was 297 days, with eight patients experiencing ongoing, complete relief. Of the 14 patients who underwent repeat neurotomy when their pain recurred, 12 (86%) regained complete relief.** In regards to the safety profile of third occipital nerve neurotomy, it should also be noted that there were no major complications, and side effects (dysesthesia, ataxia, local itchiness) were self-limited and resolved within 7-10 days, apart from one patient having a side effect for 4 weeks.

Another study was undertaken to explicitly test if the outcomes reported in the controlled trial could be replicated in conventional practice; it showed that they were.¹⁴ Of 35 patients treated, 21 (60%) obtained complete relief of pain for at least 12 weeks in the first instance and for a median duration of 44 weeks. In this study, treatment was provided at the C2-3 level in 50% of the patients.

In the third study, two clinicians evaluated their outcomes after being trained in proven technically effective lesioning techniques.¹⁵ The outcomes of all their consecutive patients over five years in their respective practices were audited. Treatment was provided at all levels from C2-3 to C6-7, and C2-3 was the most common level treated. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work (if applicable), and no further need for any other health care for their index pain. In the two practices, **74% and 61% of patients achieved a successful outcome. Relief lasted a median duration of 17–20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 20-26 months, with some 60% still having relief at final follow-up.**

These studies clearly demonstrate that 60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a duration of relief from 10-17 months. No other non-surgical treatment in the cervical spine can rival this degree and duration of relief. There are minimal to no high-quality rigorous trials of non-invasive conservative care (*i.e.* physical therapy, chiropractic, medications) for sub-occipital neck pain or cervicogenic headache, to aid in drawing comparisons to third occipital nerve neurotomy regarding efficacy or cost-effectiveness. When considering potential surgical treatments, cervical fusion is the only valid consideration. However, fusion is rarely indicated; primarily when there is C2-3 segmental instability or spondylolisthesis. Even in properly selected patients, surgery of the upper cervical spine has a relatively high morbidity and mortality, and surgery may be contraindicated in some patients. Preservation of access to a proven, effective treatment is particularly critical when there are few valid, proven, and equally safe alternative options.

An RCT establishing that the results of third occipital nerve RF neurotomy are not due to placebo effects as an absolute condition of coverage is not necessary in light of the magnitude of effects for this intervention when appropriately performed on the correct patients,¹⁶⁻¹⁸ but one important consideration has been often overlooked. It would be impossible to perform a true blinded RCT on C2-3 facet RF neurotomy. Patients who receive an effective third occipital nerve neurotomy develop time-limited, neuropathic symptoms followed by cutaneous numbness in the distribution of the nerve. The active arm would clearly be aware of such symptoms and know they received the treatment and those that receive the sham would not have such symptoms. Additionally, those that receive diagnostic third occipital nerve blocks also develop temporary numbness in the same distribution and learn that such is associated with an active block and this would be an expectation following a technically well-performed active C2-3 facet neurotomy.

It is our recommendation, consistent with local coverage determinations proposed by the Multisociety Pain Workgroup and adopted by several Medicare Contractors, that for patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using previously described techniques, third occipital nerve RF neurotomy should be a covered procedure.

Radiofrequency Denervation of the Sacroiliac Joint/Lateral Branch Radiofrequency Neurotomy (LBRFN)

We also note that United Healthcare's medical policy classifies thermal radiofrequency ablation of the sacroiliac joint, also referred to as lateral branch radiofrequency neurotomy (LBRFN), as unproven or medically unnecessary despite the fact that there are multiple randomized controlled trials that have demonstrated the efficacy of the procedure.^{19,20} The evidence review included in the policy omits an important randomized controlled trial by Patel *et al* (attached) that included 51 patients and compared the efficacy of LBRFN using cooled radiofrequency (a type of thermal radiofrequency neurotomy) to a sham intervention for sacroiliac joint pain.² Statistically significant changes in pain, physical function, disability, and quality of life were found at 3-month follow-up, with all changes favoring the LBRFN group. At 3-month follow-up, 47% of treated patients and 12% of sham subjects achieved treatment success. At 6 and 9 months, respectively, 38% and 59% of treated subjects achieved treatment success. The treatment group showed significant improvements in pain, disability, physical function, and quality of life as compared with the sham group.

In addition, a recently completed multidisciplinary, multi-society effort to develop appropriate use criteria for sacroiliac interventions concluded that LBRFN is an appropriate treatment 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.

An excerpt from the manuscript (attached), which describes the results, is included below:

“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 2-3 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 3 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 was most relevant for those with 50-75% pain relief and in those with only 2-3 months of symptoms.”²¹

We hope that this information, as well as any dialogue and collaboration between United Healthcare and the Spine Intervention Society, will lead to the establishment of a reasonable coverage policy that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@SpineIntervention.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Timothy Maus".

Timothy Maus, MD
President
Spine Intervention Society

Attachments:

Patel N, Gross A, Brown L, Gekht G. A randomized, placebo controlled study to assess the efficacy of lateral branch denervation for chronic sacroiliac joint pain. *Pain Med* 2012;13:383–98.

MacVicar J, Kreiner DS, Duszynski B, Kennedy DJ. Appropriate use criteria for fluoroscopically guided diagnostic and therapeutic sacroiliac interventions: results from the Spine Intervention Society convened multispecialty collaborative. *Pain Medicine* 2017;18:2081-2095.

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A Randomized, Placebo-Controlled Study to Assess the Efficacy of Lateral Branch Neurotomy for Chronic Sacroiliac Joint Pain

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No direct compensation was given to the physicians or staff who performed these procedures. No conflicts of interest are noted by participating study physicians or staff.

Abstract

Objective. The objective of this study was to compare the efficacy of lateral branch neurotomy using cooled radiofrequency to a sham intervention for sacroiliac joint pain.

Design. Fifty-one subjects were randomized on a 2:1 basis to lateral branch neurotomy and sham groups, respectively. Follow-ups were conducted at 1, 3, 6, and 9 months. Subjects and coordinators were blinded to randomization until 3 months. Sham subjects were allowed to crossover to lateral branch neurotomy after 3 months.

Subjects. Subjects 18–88 years of age had chronic (>6 months) axial back pain and positive response to dual lateral branch blocks.

Interventions. Lateral branch neurotomy involved the use of cooled radiofrequency electrodes to

ablate the S1–S3 lateral branches and the L5 dorsal ramus. The sham procedure was identical to the active treatment, except that radiofrequency energy was not delivered.

Outcome Measures. The principal outcome measures were pain (numerical rating scale, SF-36BP), physical function (SF-36PF), disability (Oswestry disability index), quality of life (assessment of quality of life), and treatment success.

Results. Statistically significant changes in pain, physical function, disability, and quality of life were found at 3-month follow-up, with all changes favoring the lateral branch neurotomy group. At 3-month follow-up, 47% of treated patients and 12% of sham subjects achieved treatment success. At 6 and 9 months, respectively, 38% and 59% of treated subjects achieved treatment success.

Conclusions. The treatment group showed significant improvements in pain, disability, physical function, and quality of life as compared with the sham group. The duration and magnitude of relief was consistent with previous studies, with current results showing benefits extending beyond 9 months.

Key Words. Sacroiliac; Pain; Radiofrequency; Ablation; Neurotomy; Lateral

Introduction

The sacroiliac joint (SIJ) has the requisite innervation to be a potential source of low back pain [1–4]. Studies have suggested that approximately 15% of undiagnosed chronic axial low back pain may originate from the SIJ complex [5–7]. The prevalence is higher in patients with low back pain after lumbar fusion procedures, with rates as high as 32% and 43% [8–10]. The condition also appears to be more common in older patients [7]. Treatment options include conservative management and injections with local anesthetic and corticosteroids. Conservative management, including physiotherapy and chiropractic, has yet to be evaluated in a controlled study on subjects with injection-confirmed SIJ pain [11]. Controlled studies on intra-articular injections have demonstrated moderate- to long-term pain relief in some subjects, but no studies have provided a high level of evidence [12–14]. Periarticular injections have been shown to provide good

od short-term relief in controlled studies, highlighting the role of extra-articular sources of pain [14–16]. SIJ fusion has been suggested as a treatment alternative in patients with pelvic rim disruption, but high level of evidence for this procedure has yet to emerge.

In recent years, there has been a growing interest in the use of radiofrequency (RF) to treat low back pain stemming from the SIJ. A number of retrospective and prospective case series have reported largely positive results [17–24]. Treatment techniques and study outcomes, however, have varied across these studies with a lack of consensus on best practices. Earlier studies used monopolar, thermal RF, but more recent studies have used what is referred to as cooled RF, in which electrodes are internally cooled to produce larger thermal lesions [22,24,25]. These studies hypothesized that larger lesions compensate for the variability in location of the target lateral branches. A controlled study that used cooled RF to target the L5 dorsal ramus and the lateral branches of the S1–S3 dorsal foramina reported treatment success in 64% and 57% of patients at 3 and 6 months, respectively, with some subjects continuing to experience relief beyond 1 year [25]. A subsequent study analyzed demographic and clinical variables of a cohort of patients who received lateral branch neurotomy and revealed that using cooled RF, but not monopolar RF, was the only positive predictive factor for treatment success [26].

Although the previous controlled study of lateral branch RF neurotomy reported successful outcomes, its sample size was small, and its results have not been replicated [25]. The present study was, therefore, undertaken to compare the outcomes of cooled RF and placebo in a larger group of patients.

Methods

This study was conducted in a private practice pain management department of an ambulatory center. Approval for this study was obtained from the Patient Advocacy Council Institutional Review Board (Mobile, AL, USA).

Study Design

To detect a significant difference in pain reduction between the groups, power calculations determined the need for 51 subjects in this study, with 34 subjects in the treatment group and 17 in the sham group, according to a 2:1 randomization scheme ($\alpha = 0.05$; $\beta = 0.1$). This sample size was derived using an expected reduction of 3.5 on the numerical rating scale (NRS) for pain in the treatment group and a reduction of 1.0 in the control group. These estimates of treatment and sham effects were based, respectively, on controlled studies by Cohen et al. and Pauza et al. [25,27].

Recruitment and Screening

Patients in this study were recruited between July 2008 and July 2010. They were recruited from the practice of

the senior author, from colleagues, and via advertisements in local print media. An initial phone interview was conducted for individuals responding to advertisements to determine appropriateness for study. Individuals deemed appropriate via telephone interview and those referred by other physicians then underwent in-person screening with study coordinators and physicians. No financial inducements were provided for participation in the study.

The inclusion criteria were as follows: predominantly axial pain below the L5 vertebrae; axial pain lasting longer than 6 months; 3-day average NRS between 4 and 8; age greater than 18 years; failure to achieve adequate improvement with comprehensive non-operative treatments, including but not limited to activity alteration, non-steroidal anti-inflammatory, physical and/or manual therapy, and fluoroscopically guided injections of steroids into the SIJ or sacroiliac ligaments; other possible sources of low back pain reasonably excluded (by means of physical exam, medical history, and magnetic resonance imaging/computed tomography/X-ray as required), including but not limited to bone fractures, the hip joint, symptomatic spondylolisthesis, tumor, and other regional soft tissue structures. Patients with history of potentially confounding intervertebral disc disease or zygapophyseal joint pain were excluded, but discography and/or medial branch blocks were not uniformly used to screen for these conditions. The exclusion criteria were as follows: a Beck's Depression Inventory score of greater than 20; irreversible psychological barriers to recovery; spinal pathology that may impede recovery such as spondylolisthesis at L5/S1, or scoliosis; symptomatic moderate or severe foraminal or central canal stenosis; systemic infection or localized infection at anticipated introducer entry site; concomitant cervical or thoracic pain greater than 2/10 on a NRS scale; uncontrolled or acute illness; chronic severe conditions such as rheumatoid/inflammatory arthritis; pregnancy; active radicular pain; immunosuppression (e.g., AIDS, cancer, diabetes, surgery <3 months ago); worker's compensation, injury litigation, or disability remuneration; allergy to injectates or medications used in the procedure; high narcotics use (>30 mg morphine daily or equivalent); active smokers (termination for at least 6 months with no smoking during follow-up period were acceptable with caution); subject unwillingness to consent to the study.

Subjects meeting all the aforementioned criteria were then screened with two sets of anesthetic blocks. The blocks were performed on the symptomatic side. Patients with bilateral symptoms were blocked bilaterally. First, the lateral branches of S1–S3 were blocked using the following method. Using C-arm fluoroscopy, an anterior-posterior image through the L5–S1 disc space was obtained. The C-arm was tilted sufficiently to visualize the posterior sacral foramina at S1, S2, and S3. Once visualized, 25G spinal needles were advanced to the surface of the sacrum 3–10 mm lateral to each posterior sacral foramen. Needle positions at the S1–S3 levels corresponded to the 3:00 position on a clock face on the right side and the 9:00 position on the left side. A lateral image

was checked to confirm appropriate depth of placement on the sacral surface. After confirming needle placement, 0.5 cc of 0.5% bupivacaine was injected at each level. The dorsal ramus of L5 was then blocked as described in the ISIS practice guidelines [28]. After confirming needle placement in the notch between the sacral ala and the S1 superior articular process, 0.5 cc of 0.5% bupivacaine was injected. Volumes did not exceed 2 cc total for unilateral injections and 4 cc total for bilateral injections. Corticosteroids were not administered as part of the diagnostic blocks. Subjects were not given any sedation (including oral sedation) and encouraged not to take any pain medication around the time of the diagnostic block in an attempt to allow for more accurate assessment of relief. To be considered as having a positive response to the block, subjects were required to have greater or equal to 75% relief of their index pain for between 4 hours and 7 days following the injections. This blocking protocol was repeated on a separate day, after a return to baseline pain. Subjects achieving 75% relief of their index pain after both blocks were required to return to baseline pain before entry into the study.

Randomization and Primary Treatment

At enrollment, a baseline evaluation of all subjects was completed, and subjects were randomized on a 2:1 basis to either the treatment group or the sham group using pre-sealed envelopes given by a nurse not involved in the study. Procedures were completed within 60 days of enrollment. Both treatment and sham procedures were performed in a fluoroscopy suite equipped with a C-arm. Preceding both treatment and sham procedures, patients received local anesthetic and moderate sedation. Under the supervision of a board certified anesthesiologist and CRNA, patients were placed on a low-dose continuous propofol infusion with or without opioid and benzodiazepine supplementation at the discretion of the anesthesia team. Patients remained communicative throughout the procedure. At this time, the randomization code was revealed to the machine operator and physician. The generator operator controlled whether RF energy was applied to the patient. The equipment arrangement in the fluoroscopy suite allowed physicians to view the generator screen during the procedure and thereby gain knowledge of group assignment. Thus, physician blinding was not possible. The patient remained visually isolated from the equipment and was exposed to typical equipment noises regardless of treatment group. To further ensure blinding, the patient was kept out of contact with other study subjects postoperatively. Those subjects who received RF were thereby classified as “treatment” subjects, and those who did not receive RF were classified as “sham” subjects.

The following technical description is applicable to both treatment and sham procedures, except that RF energy was not delivered to sham subjects. Probe placements, procedure duration, equipment sounds, and visual indications to the patients in both groups were identical.

First, the L5 dorsal ramus was lesioned with a cooled RF Snergy probe (Kimberly Clark Health Care, Roswell, GA, USA) in the following manner. The patient was placed in the prone position and the target anatomy for electrode placement was identified using C-arm fluoroscopy. First, an anterior-posterior view was obtained by imaging through the L5-S1 disc space. The C-arm was then rotated obliquely 20°–30° such that the junction between the S1 superior articular process and the sacral ala was visualized. The specific bony target for needle placement was the notch between these two bones, just inferior to the cranial-caudal midline of the notch. The introducer was advanced “down the beam” until bone contact at the target. A lateral view confirmed that the tip of the stylet was no deeper than the mid aspect of the superior articular process (SAP). The stylet was removed from the introducer and was replaced with the Snergy Probe (Kimberly Clark Health Care). A lateral view confirmed the tip of the probe to be 2 mm proximal to the tip position previously observed with the stylet, which allowed for distal projection of the lesion. Once accurate electrode placement was confirmed, 0.5 cc of 2% lidocaine and 0.5 cc of 0.75% bupivacaine was injected through the introducer to reduce discomfort and ensure blinding. RF energy was then applied for 150 seconds, at a set temperature of 60°C using a Pain Management Radiofrequency Generator (Kimberly Clark Health Care). During RF delivery, subjects were monitored for any new symptoms and pain in the groin, thigh, lower leg, or foot.

After coagulation of the L5 dorsal ramus, the sacral lateral branches of S1, S2, and S3 were targeted. C-arm fluoroscopy was used to visualize through the L5/S1 disc space. The C-arm was then tilted until the S1, S2, and S3 posterior sacral foramina were successively visualized. Using this imaging strategy, 27-gauge 3.5-in. Quincke needles were placed at the lateral margins of the S1, S2, and S3 posterior sacral foramina in order to obtain a more definitive localization of these structures via tactile feedback.

The first bony target for electrode placement was a point 7 mm lateral to the 27-gauge needle at the lateral margin of the S1 posterior sacral foramen. Prior to skin puncture, the area over the target entry point was infiltrated with 1% lidocaine. An introducer with stylet was then advanced through the skin and overlying tissue until contact was made with the target point on the sacrum. A stainless steel ruler (Epsilon Ruler, Kimberly Clark Health Care) was used to measure the distance between the posterior sacral foramen and the introducer. The stylet was then replaced with the 17-gauge, 75-mm cooled electrode with 4-mm active tip (Kimberly Clark Health Care), which, being 2 mm shorter than the stylet, came to a final position of 2 mm from the surface of the sacrum. A lateral fluoroscopic image confirmed that the RF probe was not within the sacral canal. Impedance was then confirmed to be between 100 and 500 Ω ; if outside this range, the electrode was repositioned slightly by reintroducing the stylet and slightly altering the location of the introducer. RF energy was then delivered for 150 seconds, at a set

temperature of 60°C. In order to form an arc-shaped wall of heated tissue lateral to the S1 posterior sacral foramen, two additional lesions were created at that level. After removing the electrode and reinserting the stylet, the introducer was angled cranially and medially to a bony target 7 mm from the first lesion target. The epsilon ruler was used to judge distance between targets, and the lateral edge of the posterior sacral foramen. After applying RF to create the second lesion, the introducer was angled caudally to a position 7 mm inferior from the first target. RF was applied to create the third lesion and complete the thermo-coagulation blockade of the lateral branches at S1. The same method was used to lesion lateral to the S2 and S3 posterior sacral foramina; however, only two lesions were created lateral to S3. For reference, right-sided S1 and S2 lesions corresponded to 2:30, 4:00, and 5:30 positions on the face of a clock; left-sided S1 and S2 lesions corresponded to 6:30, 8:00, and 9:30 on the face of a clock. For S3, right-sided lesions corresponded to 1:30 and 3:00 on a clock face, and left-sided lesions corresponded to 9:00 and 10:30. Subjects requiring bilateral treatment received contralateral RF treatment during the same procedural session. Post-lesioning, 1 cc of a 1:1 mixture of 2% lidocaine and 0.75% bupivacaine was given at each level to control pain in the immediate postoperative period.

Subjects were prescribed analgesics for postoperative pain. Activity was avoided the day of the procedure, and excessive activity was avoided for 1–3 days following the procedure. Subjects remained out of contact with anyone privy to randomization details.

Outcome Measures and Follow-Up

Patient reported outcomes for pain, physical function, disability, global perceived effect (GPE), and quality of life were obtained using a number of instruments. A NRS was used to assess pain. The Oswestry disability index (ODI) was used to assess disability. The Short Form SF-36 (version 1) was used to assess bodily pain and physical function using the respective subscales: SF-36BP and SF-36PF. Quality of life was measured using the Assessment of Quality of Life (AQoL) assessment tool. GPE was measured by having subjects rate their index pain on a 7-item scale with the following options: pain is completely gone; pain has decreased a lot; pain has decreased; pain is the same; pain has increased; pain has increased a lot; and pain is the worst possible. To assess blinding, patients were asked post-procedure if they believed active treatment had been received. All questionnaires were administered by a study coordinator blinded to subject randomization. Physicians involved in performing procedures were not involved in follow-up patient visits. Subjects in the treatment group were scored with these instruments at baseline and at 1-, 3-, 6-, and 9-month post-procedure. Subjects in the sham group were scored at baseline and post-procedure at 1 and 3 months.

Both assessors and subjects were blinded to randomization at the 1-month and 3-month follow-up time-points.

Unblinding occurred after 3-month follow-up data were collected. After unblinding at 3-months, subjects in the sham group were offered RF lateral branch neurotomy and those who opted to crossover were followed-up at 1, 3, and 6 months. Subjects who crossed-over from the sham group to receive lateral branch neurotomy were referred to as “crossover” subjects.

Statistical Measures and Study Endpoints

Means and standard deviations were calculated for continuous variables and compared with *t*-tests. For categorical variables, data were summarized in frequency distributions and compared with Fisher's exact test. Results for proportions are reported hereafter as percentages, followed by confidence intervals calculated at the 95% level. Statistical significance was considered to be $P < 0.05$.

The primary endpoint in this study was the comparison of mean change from baseline in NRS between treatment and sham groups at the 3-month follow-up time-point. Secondary endpoints in this study included comparison of mean changes from baseline between treatment and sham groups in ODI, SF-36BP, and SF-36PF. The proportions of subjects demonstrating a successful response to treatment were compared between groups, with treatment success defined as a $\geq 50\%$ decrease in NRS pain score corroborated by one of the following: 1) a 10-point increase (improvement) in SF-36BP or 2) a 10-point decrease (improvement) in ODI. Other secondary endpoints were GPE and comparison of mean quality of life (AQoL). For subjects who dropped out of the study after the 3-month time-point, the last-observation carried-forward method of data imputation was used to calculate subsequent results. Subjects who did not complete a baseline outcome questionnaire for an outcome tool were excluded from mean change analysis at subsequent time-points for that outcome; this applied to three subjects for SF-36PF, two subjects for SF-36BP, four subjects for ODI, and four subjects for AQoL. The crossover group was not compared with the treatment or sham groups as the study was not designed to make such comparisons: crossover subjects received treatment with lateral branch neurotomy in an unblinded manner, as opposed to the original treatment group that received the procedure in a blinded manner. This also precluded the combination of data from the treatment and crossover groups.

Results

Demographics and Complications

There were 304 patients screened by telephone and in-clinic for inclusion in this study (Figure 1). Two hundred fifty-three individuals were excluded from participation for a multitude of reasons: 153 did not meet the clinical inclusion criteria, 97 declined to be randomized or comply with protocol, 2 did not report for randomization, and 1 died before randomization. Fifty-one subjects were

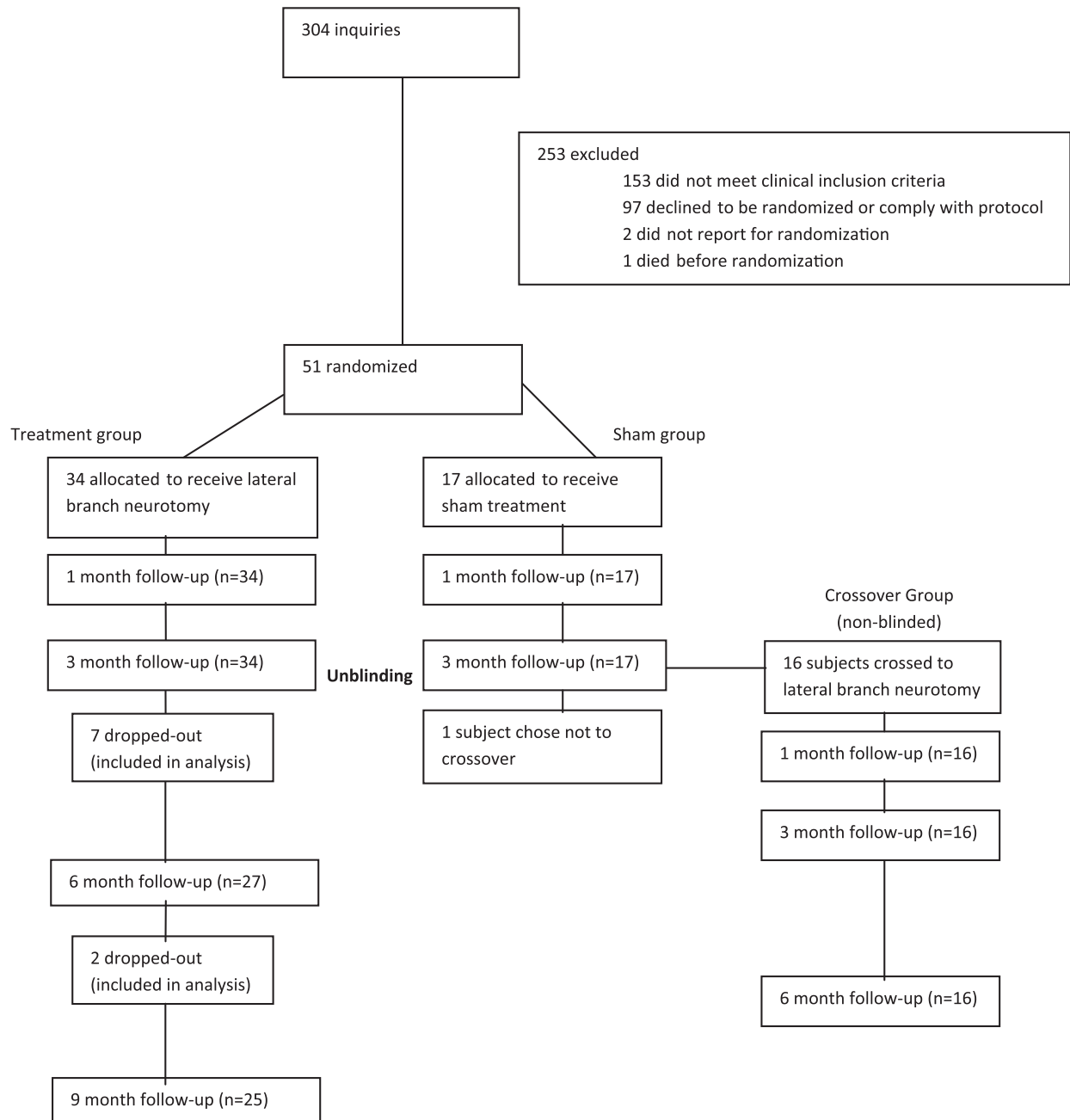


Figure 1 Chart showing progression of a randomized, placebo-controlled trial of lateral branch neurotomy using cooled radiofrequency for sacroiliac joint mediated low back pain.

deemed eligible, consented, and randomized in the study. After randomization, 34 subjects were allocated to the treatment group and 17 to the sham group. All enrolled subjects participated in the study until the unblinding at 3 months. Seven treatment subjects dropped out of the study after the 3-month follow-up, and an additional two dropped out after the 6-month follow-up. One sham subject chose not to crossover to receive lateral branch neurotomy.

In the treatment and sham groups, respectively, 64% (47–82%) and 56% (32–81%) of subjects were able to accurately guess which procedure they received ($P = 0.584$). Blinding was satisfactory as these rates were not significantly different from chance.

No serious complications were reported for the 50 lateral branch neurotomy procedures or for the 17 sham procedures completed during this study. A small proportion of

Table 1 Demographic characteristics and clinical features recorded at baseline of patients randomized to lateral branch neurotomy or sham study groups

Feature	Lateral Branch Neurotomy (N = 34)		Sham (N = 17)		P Value*
	N	%	N	%	
Male	11	32	3	18	0.334
Female	23	68	14	82	
Age (mean $\pm$ SD), years	56 $\pm$ 15 (range: 18–88)		64 $\pm$ 14 (range: 43–84)		0.087
Work status:					
Unemployed because of back pain	1	3	1	6	0.259
Unemployed not because of back pain	11	32	9	53	
Working	22	65	7	41	
Duration of pain					
6–12 months	6	18	1	6	0.584
12–24 months	5	15	3	18	
>24 months	22	65	13	77	
Missing	1	3	0	0	
Previous treatment					
Physiotherapy	7	21	2	12	0.699
Bed rest	5	15	3	18	1.000
Anti-inflammatory drugs	23	68	11	65	1.000
Opioids	12	35	11	65	0.073
Injections	14	41	7	41	1.000
Chiropractics	8	24	3	18	0.731
Referred pain					
In buttock	23	68	13	77	0.746
In thigh	11	32	9	53	0.225
In leg	9	27	6	35	0.532

*0.05; SD = standard deviation.

subjects reported soreness or numbness at the introducer sites in the 2 weeks following treatment. One subject developed shingles at the introducer site, but this was deemed unrelated to the treatment.

Analysis of demographic characteristics and clinical features recorded at baseline revealed no statistically significant differences between the two groups (Table 1). Also,

no statistically significant differences were found between baseline values of outcome measures (Table 2).

Pain, Physical Function, and Disability

The mean change from baseline in pain, physical function, and disability outcomes are reported in Table 3 for treatment and sham groups at each time-point. Mean

Table 2 Baseline outcome measures of patients randomized to lateral branch neurotomy or sham study groups

Outcome Measure	Lateral Branch Neurotomy		Sham		P Value
	Mean	SD	Mean	SD	
NRS for pain (0–10)	6.1 (N = 34)	1.3	5.8 (N = 17)	1.3	0.370
SF-36 (0–100)					
SF-36 bodily pain	40 (N = 33)	15	43 (N = 16)	10	0.525
SF-36 physical functioning	50 (N = 32)	20	47 (N = 16)	24	0.707
Oswestry disability scale (0–100)	37 (N = 32)	14	35 (N = 15)	10	0.639
AQoL	0.60 (N = 33)	0.19	0.54 (N = 14)	0.16	0.346

AQoL = Assessment of Quality of Life; NRS = numerical rating scale; SD = standard deviation.

Table 3 Pain, physical function, and disability outcomes of subjects who received lateral branch neurotomy or sham procedures

Outcome Measure	Treatment		Sham		P Value
	Mean	SD	Mean	SD	
NRS for pain (0–10)	(N = 34)		(N = 17)		
1-month change	–2.7	2.6	–1.7	2.0	0.160
3-month change	–2.4	2.7	–0.8	2.4	0.035
6-month change	–2.5	2.6	—	—	—
9-month change	–2.7	2.7	—	—	—
SF-36 bodily pain (0–100)	(N = 33)		(N = 16)		
1-month change	15	17	2	11	0.006
3-month change	16	26	–1	13	0.019
6-month change	14	22	—	—	—
9-month change	20	23	—	—	—
SF-36 physical functioning (0–100)	(N = 32)		(N = 16)		
1-month change	10	17	5	12	0.238
3-month change	14	19	3	12	0.040
6-month change	14	23	—	—	—
9-month change	18	21	—	—	—
Oswestry disability scale (0–100)	(N = 32)		(N = 15)		
1-month change	–12	14	–4	11	0.046
3-month change	–11	17	2	6	0.011
6-month change	–13	16	—	—	—
9-month change	–15	16	—	—	—

NRS = numerical rating scale; SD = standard deviation.

Note: Improvements in numerical rating scale and Oswestry disability index scores manifest as decreases, and improvements in SF-36BP and SF-36PF manifest as increases.

improvement in NRS pain score at the 3-month time-point for the treatment group was significantly greater than that for the sham group. The treatment group achieved a significantly greater improvement in SF-36BP at the 1- and 3-month time-points. The treatment group achieved a significantly greater improvement in SF-36PF at the 3-month time-point. The treatment group achieved a significantly greater improvement in ODI at the 1- and 3-month time-points. Individual NRS, SF-36BP, ODI, and SF-36PF outcomes at 3-month follow-up are shown in Figure 2. The distribution of outcome states for all treatment subjects is shown in Figure 3.

To evaluate the proportion of patients who achieved a clinically meaningful outcome, treatment success was defined as a $\geq 50\%$ NRS decrease corroborated by one of the following: 1) a 10-point increase in SF-36BP or 2) a 10-point decrease in ODI. Sixteen out of 34 treatment subjects (47%; 30–65%) and 2 out of 17 sham subjects (12%; 1–36%) met the definition of treatment success at 3 months ($P = 0.015$; Figure 4). The NRS, ODI, SF36-BP, and SF36-PF outcomes for each patient are presented in Figure 2. At 6 and 9 months, respectively, 13 out of 34 (38%; 22–56%) and 20 out of 34 (59%; 41–75%) treatment subjects had successful outcomes. Treatment success in subjects who crossed over from sham to lateral branch neurotomy was observed in 7 out of 16 subjects (44%; 20–70%) at both 3 and 6 months.

Global Perceived Effect

In the current study, a GPE score was considered positive if the subject rated GPE as “pain has decreased a lot,” or “pain is completely gone.” At the 3-month time-point, 47% (29–65%) of treatment subjects had a positive GPE response, with 25% of subjects specifying “pain has decreased a lot” and 22% of subjects specifying “pain is completely gone” (Table 4). At the 6-month time-point, 45% (28–64%) of treatment subjects had a positive GPE response, with 27% of subjects specifying “pain has decreased a lot” and 18% of subjects specifying “pain is completely gone.” At the 9-month time-point, 67% (48–82%) of treatment subjects had a positive GPE response, with 52% of subjects specifying “pain has decreased a lot” and 15% of subjects specifying “pain is completely gone.” In the sham group, at the 3-month follow-up time-point, 8% (0–36%) of subjects had a positive GPE response, with 8% of subjects specifying “pain has decreased a lot” and no subjects specifying “pain is completely gone.” A significantly greater proportion of subjects in the treatment group reported a positive GPE response at 3 months, as compared with the sham group ($P = 0.017$). After cross-over to lateral branch neurotomy, at the 3-month time-point, 50% (23–77%) of subjects had a positive GPE response, with 36% of subjects specifying “pain has decreased a lot” and 14% of subjects specifying “pain is completely gone” (Table 4). At the 6-month time-point,

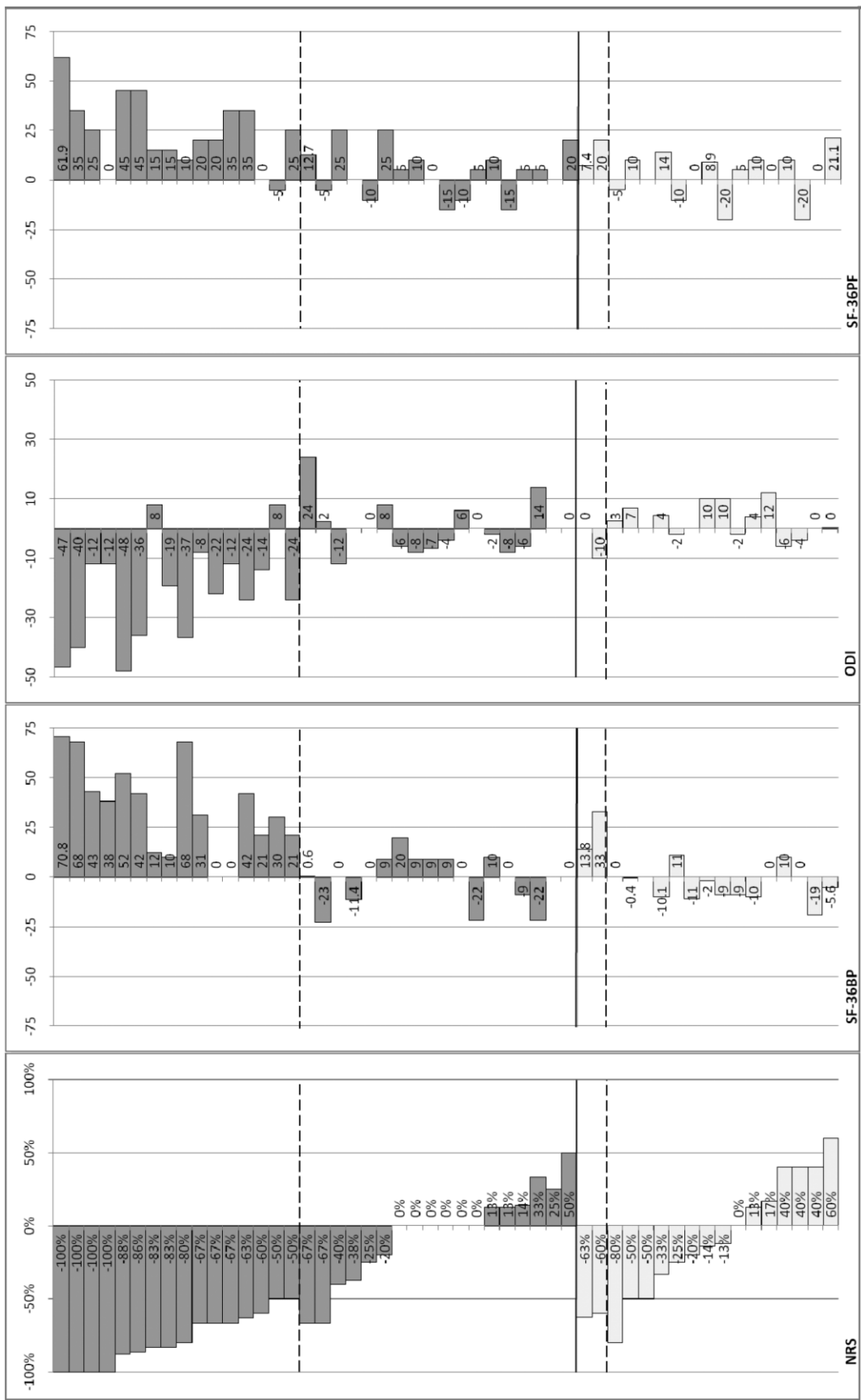


Figure 2 Change in numerical rating scale (NRS), SF-36BP, Oswestry disability index (ODI) and SF-36PF at the 3-month time-point by study subject. Note: Dark gray bars represent treatment subjects, light gray bars represent sham subjects. Dotted lines separate subjects meeting the criteria for treatment success (top) from those not meeting the criteria (bottom) within each treatment group. Data for each subject run horizontally across all four outcome measures. Improvements in NRS and ODI manifest as negative changes; improvements in SF-36BP and SF-36PF manifest as positive changes.

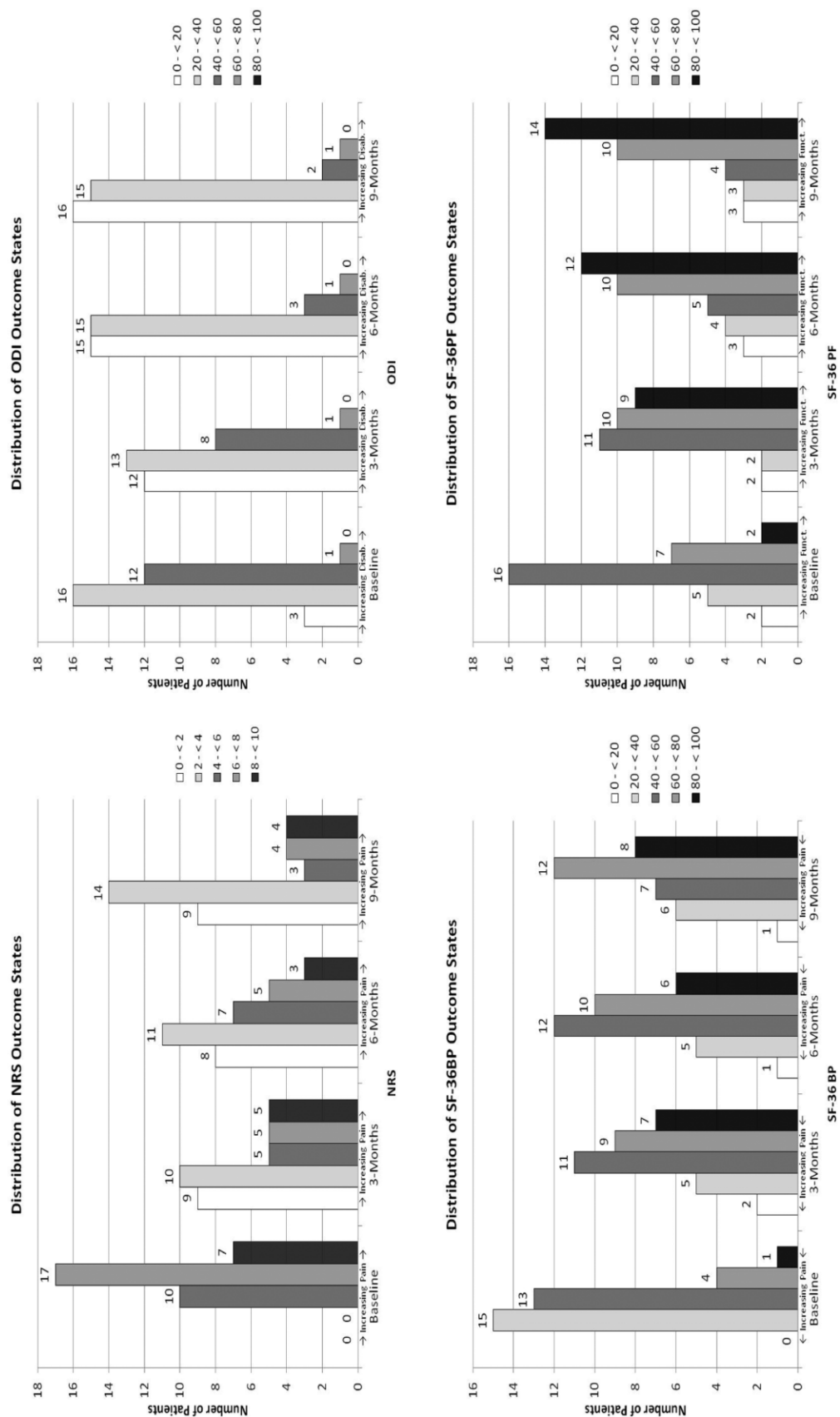


Figure 3 Distribution of outcome states for numerical rating scale, Oswestry disability index, SF-36BP, and SF-36PF, among treatment subjects, by time-point.

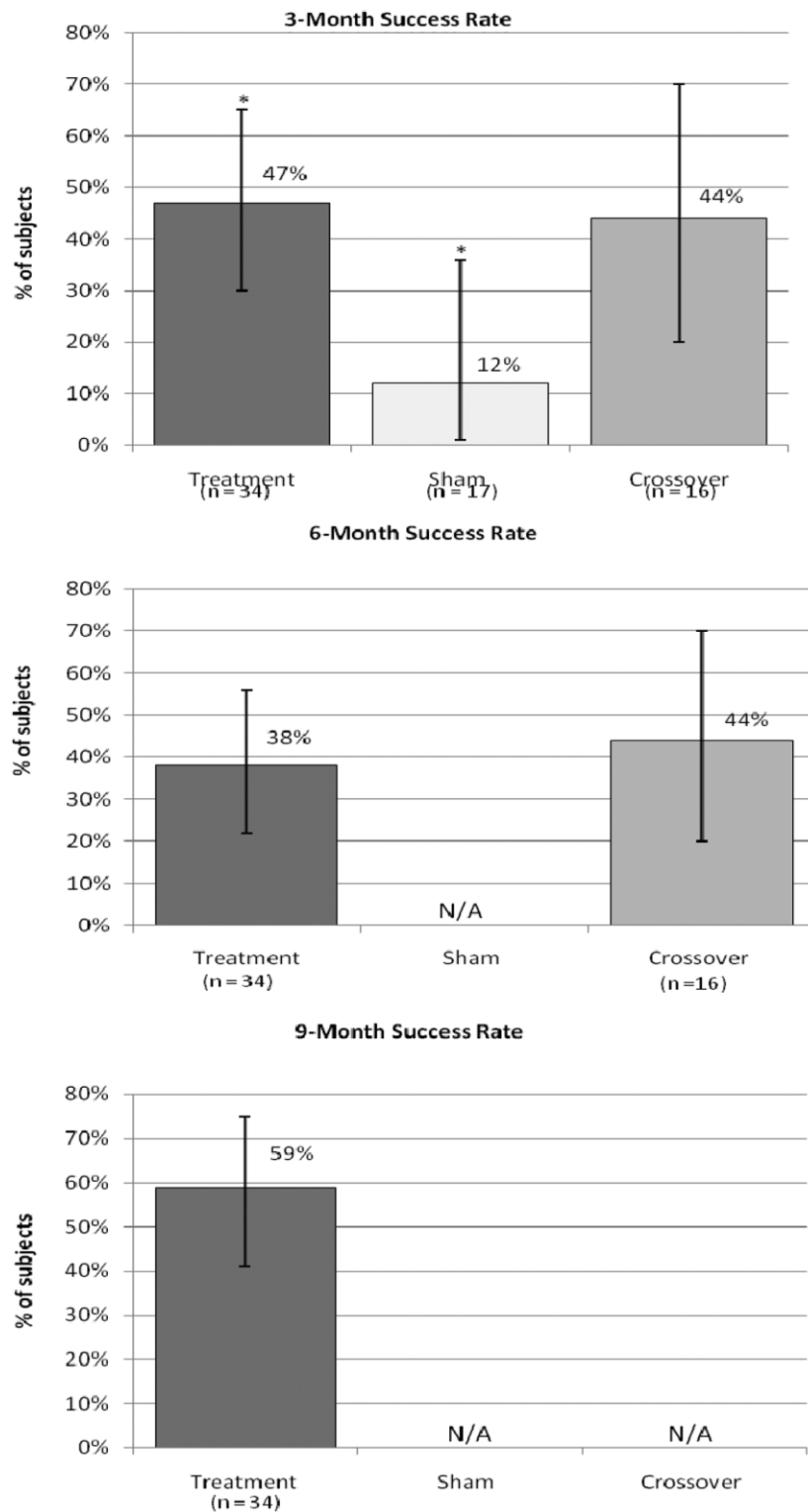


Figure 4 Percent of subjects meeting criteria for successful treatment response, by time-point and study group. Whiskers represent the 95% confidence interval. *Statistically significant difference at 0.05 level. Note: Treatment success defined as a $\geq 50\%$ decrease in numerical rating scale plus one of 10-point increase in SF-36BP or 10-point decrease in Oswestry disability index.

Table 4 Percent of subjects reporting a positive global perceived effect, by study group and time-point

	Treatment	Sham	Crossover
3 months	47% (29–65%)*	8% (0–36%)*	50% (23–77%)
6 months	45% (28–64%)	N/A	47% (21–73%)
9 months	67% (48–82%)	N/A	N/A

* $P < 0.05$ comparing treatment and sham groups.

Note: A positive global perceived effect was defined as patients reporting their pain as “decreased a lot” or “completely gone.”

47% (21–73%) of crossover subjects had a positive GPE response, with 40% of subjects specifying “pain has decreased a lot” and 7% of subjects specifying “pain is completely gone.”

Quality of Life

The mean AQuL scores for treatment and sham subjects were not significantly different at baseline: 0.60 ± 0.19 for treatment subjects vs 0.54 ± 0.16 for sham subjects ($P = 0.346$). At 3 months, however, a significant difference in mean AQuL scores was detected between treatment (0.69 ± 0.21) and sham subjects (0.56 ± 0.21 ; $P = 0.048$). The mean AQuL scores for each time-point are shown graphically in Figure 5, with results stratified by study group.

Discussion

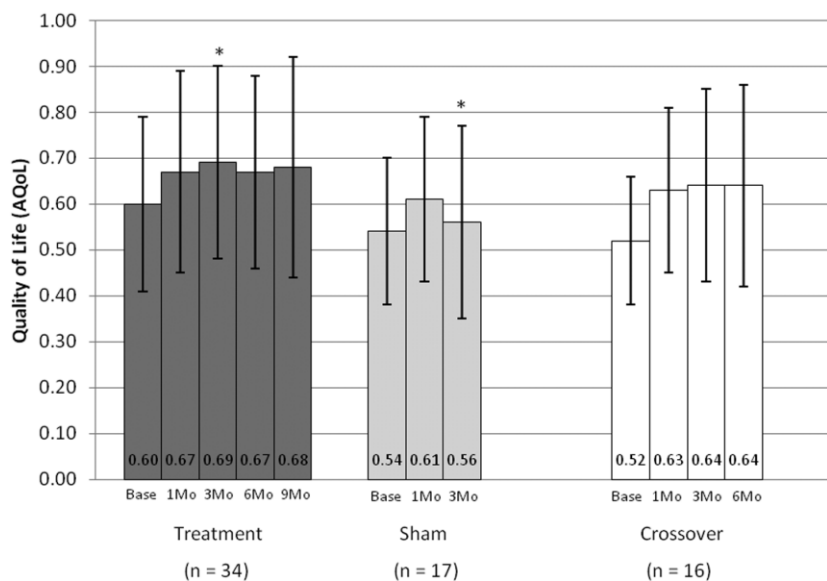
The results of this study demonstrate that among subjects with chronic low back pain stemming from the SIJ, lateral branch neurotomy affects a significantly greater pain

reduction from baseline compared with a sham treatment. Treatment subjects achieved a mean NRS decrease of 2.4, while sham subjects experienced a mean reduction of 0.8 ($P = 0.035$). The effectiveness of the treatment procedure is supported by statistically significant differences in disability and physical function improvements between groups at 3-month follow-up. This result indicates that lateral branch neurotomy with cooled RF is not a sham procedure, corroborating the results of Cohen et al. [25].

For a more thorough assessment of clinical utility, it is useful to consider the proportion of patients that demonstrated a clinically significant outcome. A review of Figure 2, which illustrates changes in outcomes for each patient, suggests that there was a bimodal response to lateral branch neurotomy. This bimodal response is masked if mean changes in outcomes are considered in isolation. Examination of the study data against a composite definition of treatment success allowed for responders and nonresponders to be delineated, and thus for the clinical relevance of treatment effects to be more effectively examined. To further assess the clinical relevance of treatment effects, a graphic representation of absolute patient outcome states is provided in Figure 3. Following treatment with lateral branch neurotomy, there is an increase in the proportion of patients occupying more-healthy outcome states. The magnitude of this change is ostensibly due to improvements in health experienced by the responder group identified in Figure 2.

Among treatment subjects, 16 out of 34 were categorized as responders at the primary endpoint of 3 months, vs two subjects in the sham group. This difference in responder rates between those receiving active and sham procedures is statistically significant and supports the aforementioned finding of a legitimate, non-placebo treatment effect from lateral branch neurotomy. The responder rate was consistent between the treatment group (47%) and

Figure 5 Mean Assessment of Quality of Life (AQuL) scores by time-point, with subjects stratified by study group. Whiskers represent standard deviation. * $P < 0.05$ comparing means between treatment and sham groups. (Note: Treatment and sham groups were blinded until 3 months, and crossover group was non-blinded at all time-points.)



the crossover group (44%) at 3 months, with both the composite variable of success and the GPE data indicating that approximately half of the treated subjects in the current study population had a successful response to lateral branch neurotomy. This finding should help prevent previous descriptive studies of lateral branch neurotomy using cooled probes, which reported largely positive results, from being dismissed as merely depicting placebo effects [22,24,26,29].

The treatment success rates derived from the composite variable correlated well with patient GPE scores, and in the author's opinion accurately represent the proportion of patients who achieved meaningful improvements. Figure 2 is designed to allow readers to evaluate treatment success against alternative composite success criteria.

Based on the treatment responder rates observed at the primary endpoint (3 months) in the current study, the number needed to treat (NNT) to get a successful outcome with lateral branch neurotomy is 3 (95% CI, 2–8). A NNT of 2–4 is indicative of an effective treatment [30]. While the NNT calculated herein comes from a single randomized controlled trial, it does provide a promising indication of what success rates practitioners may expect when using lateral branch neurotomy in carefully selected patients with chronic SIJ pain.

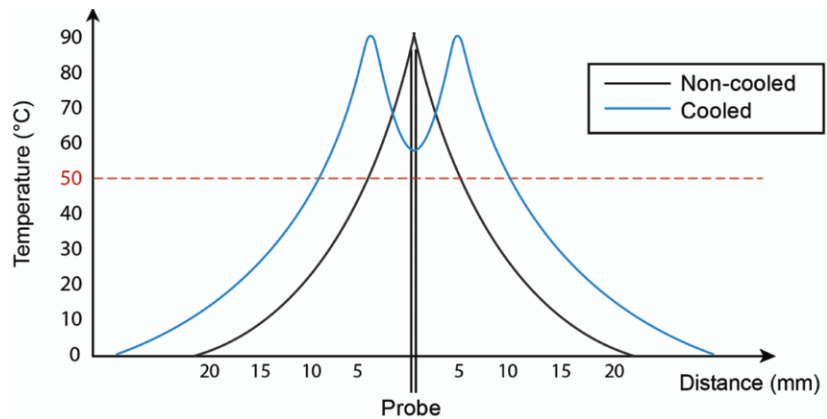
Studies of spinal neuroablative procedures have reported pain relief of approximately 9–12 months in duration, with some subjects ostensibly achieving permanent relief [31–33]. The outcomes in the current study suggest that the durability of lateral branch neurotomy is consistent with these procedures. At the 9-month time-point, 20 out of 34 subjects (59%; 41–75%) were categorized as responders. This was higher than the responder rate at 6 months at which point 13 out of 34 (38%; 22–56%) treatment subjects reported a successful outcome. The success rate at 6 months may be artificially low due to one subject who had a pain flare-up, which was resolved by 9 months, and another subject who did not meet the secondary outcome requirements for treatment success at 6 months but did so at 3 and 9 months. Furthermore, two patients were identified as having gradual improvements in outcomes across time, but not meeting the composite criteria for treatment success until 9 months. An additional subject had a discectomy and fusion of the cervical spine at 3 months and revision surgery at 6 months following complications, with treatment effects from lateral branch neurotomy ostensibly masked until 9 months when the treatment success criteria were met. Overall, these data suggest that treatment effects seen at 3 months were durable at 9 months. The data do not indicate how long these effects will last, but treatment success has been reported to last beyond 12 months in some subjects [25]. The proposed mechanism by which pain returns is the natural regeneration of ablated nociceptive nervous tissue. It is possible that treatment responders who have a return of pain would be amenable to repeat RF lesioning, as has been demonstrated in the literature for the treatment of lumbar facet joint pain with RF neurotomy [34].

Three data imputation methods were compared in the analysis of the current data: complete-case analysis, worst-case analysis, and last-observation carried-forward. The complete-case analysis gave the least conservative assessment of the data and was disregarded. The worst-case analysis, which assumed that all treatment subjects were failures, showed that treatment success was achieved in 35% (19–51%) of treatment subjects at 6 months, and 56% (39–73%) of treatment subjects at 9 months. These success rates did not differ significantly from those collected under the last-observation carried-forward imputation method: 38% (22–56%) of treatment subjects achieved success at 6 months, and 59% (41–75%) of treatment subjects achieved success at 9 months. Imputation methods which presume lack-of-effect have been criticized in the literature for penalizing studies for drop-out subjects [35]. This criticism was reflected by at least one subject in the current study who was showing a robust treatment response across all outcomes at 3 months, but had to leave the study shortly thereafter to receive epidural steroid injections for a separate pain generator. Therefore, the last-observation carried-forward data imputation technique was used for the seven subjects who dropped from the current study after 3-month follow-up and for the two subjects who dropped after 6 months. This method appears to provide a representative means of imputation for this data set; however, the worst-case analysis is also provided for reader consideration.

Subjects and assessors were unblinded after data collection at the 3-month time-point. Results of other prospective studies have shown that the majority of subjects receiving sham neurotomy treatments will report the absence of relief by 3-month follow-up [25,31]. This is consistent with the current results as 16 out of 17 sham subjects chose to crossover to receive lateral branch neurotomy (one sham subject left the study after completing 3 months in the sham group). It was assumed that having patients blinded for a longer period of time could increase the likelihood of noncompliance at follow-up evaluation and encourage the pursuit of other treatments outside of the study.

The current study suggests that roughly half of the treated subjects (both in the treatment group and those in the sham group who crossed over to receive lateral branch neurotomy) had a successful response to treatment. There are several likely reasons why the remaining subjects did not achieve treatment success. First, the diagnostics blocks did not require a complete resolution of pain, but only $\geq 75\%$ relief. Therefore, it could be expected that some patients would achieve only incomplete relief from RF lateral branch neurotomy. Second, the blocking paradigm used for patient selection did not include a placebo control, which raises the possibility that subjects exhibiting a placebo response to anesthetic injections entered the study. Third, several subjects nonresponsive to treatment had a secondary, previously unidentified pain generator with a pain map overlapping that of SIJ pain. The reliance on medical history to screen for subjects with

Figure 6 The temperature profile of thermal radiofrequency ablation with and without internal cooling. Internal cooling allows greater energy deposition in the tissue, resulting in larger effective lesion radius. The dashed line represents the 50°C isotherm, which is the effective lower limit for nerve ablation. Adapted from Goldberg et al. [44].



discogenic pain or facetogenic pain, without the use of additional specific tests such as discography or medial branch blocks, was a shortcoming of this study. Additional examples of secondary pain generators observed during follow-up in treatment nonresponders in the current study were as follows: discectomy with fusion at C3 vertebrae, followed by subsequent complications from instrumentation necessitating eventual removal; bilateral osteoarthritic knee pain; development of contralateral SIJ pain after unilateral treatment; hip pain necessitating steroid injections and eventual hip replacement; and development of painful shingles at treatment introducer site. The likelihood of presenting with a secondary pain generator increases in the elderly as aging of the body leads to an increased prevalence of pain-generating conditions. In the current study, 39% of subjects were between 60 and 90 years of age, and an additional 39% were between 50 and 59. A fourth potential explanation for the lack of treatment success among nonresponders is the possibility of ventral innervation of the SIJ, which is not targeted by the lateral branch neurotomy procedure. Recent evidence has confirmed the existence of ventral innervation of the SIJ by distension of the joint to elicit pain following blockade of the extra-articular dorsal innervation [36]. This explanation, however, should be abrogated by the current use of a diagnostic blocking technique that selects exclusively for dorsal SIJ pain. Future study results could be improved by using a diagnostic block that more closely replicates the lesioning targets of the current lateral branch neurotomy technique [36]. Finally, treatment failure can be due to incomplete denervation of the dorsal innervations due to technical or procedural variability.

In the current study, sham treatment mimicked the actual treatment in all respects, except that there was no delivery of RF energy. Thus, the significantly better outcomes observed in the treatment group, as compared with the sham group, suggest that the delivery of RF energy to posterior afferent nociceptive pathways has the ability to disrupt pain signaling from the SIJ complex.

The procedural technique targets the S1–S3 lateral branches and the L5 dorsal ramus, which together comprise the known dorsal innervations of the SIJ [1–4,19].

While the location of the L5 dorsal ramus maintains a consistent relationship with the surrounding bony landmarks, a central challenge of this procedural technique is to compensate for the inconsistent location of the sacral lateral branches. There exists patient-to-patient and level-to-level variability in both the number and the location of the lateral branches along the posterior sacrum [19,37,38]. Previous studies evaluating lateral branch neurotomy using cooled RF have hypothesized that larger lesions could compensate for this variability in lateral branch location [22,24,25]. Procedurally, this is accomplished by overlapping the thermal lesions to create confluent “strips” of lesioned tissue lateral to the S1, S2, and S3 posterior sacral foramina. The specific lesion targets around each of the foramina are a geometric consequence of the lesion size and the known variability of the lateral branches.

Internally cooled RF electrodes were introduced in the 1990s for tumor ablation and cardiac ablation [39–41]. They were developed to increase the maximum volume of tissue ablation attainable by a monopolar RF electrode [39]. The fundamental premise of the cooled RF electrode is that a circulating coolant will prevent the condition of high impedance at the interface between the tissue and electrode. This allows a higher RF output power and thus a larger volume lesion (Figure 6). The SInergy probe used for this study creates spherical lesions of 8–10 mm in diameter [25,42]. The utility of a larger, spherical lesion for electrode placement perpendicular to bone is illustrated in Figure 7.

The meticulous positioning of large volume lesions around each posterior sacral foramen in order to sever the afferent input from the SIJ is a prerequisite to achieving successful outcomes for this procedure. A retrospective study by Cohen et al. analyzed clinical and demographic variables as predictors of lateral branch neurotomy success and found cooled RF, as compared with conventional RF, to be the only positive predictor of treatment success [26].

Lateral branch neurotomy using cooled RF has been recommended as the treatment option for subjects who have failed to achieve relief, or achieved only short-term relief,

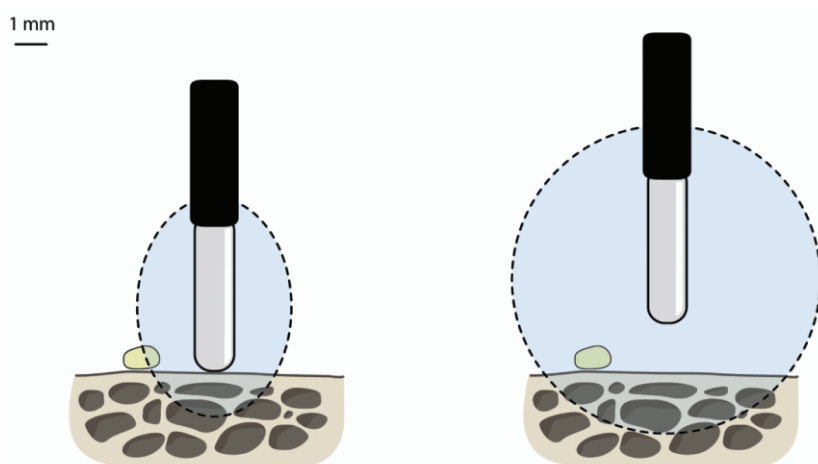


Figure 7 Illustrations of the possible relationship between electrodes and target lateral branch nerves lying across the surface of the sacrum. Both the conventional (non-cooled) electrode on the left and the cooled radiofrequency (RF) electrode on the right can substantially encompass the nerve if precisely positioned, but the cooled RF electrode has a larger effective radius, increasing the likelihood that the thermal lesion will fully encompass the target nerve. The illustration on the left is adapted from Bogduk et al. [45]. The geometry of the cooled lesion on the right is referenced from Cohen et al. and scaled for comparison [25].

from intra-articular SIJ injections [43]. This is the second randomized, controlled study evaluating lateral branch neurotomy for the treatment of low back pain stemming from the SIJ to be conducted. The current results in this patient population showed improvements in measures of pain, disability, physical function, and quality of life. This study further supports the recommendation of cooled RF lateral branch neurotomy for persistent SIJ pain [43].

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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?
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	Intra-articular SIJ injection of local anesthetic without steroid?
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)		Intra-articular SIJ injection of steroid alone?
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?
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	Intra-articular SIJ injection of local anesthetic without steroid?
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)		Intra-articular SIJ injection of steroid alone?
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?
Normal imaging of the lumbar spine and pelvis	Provocation tests of SIJ negative	History of pelvic trauma	Intra-articular SIJ injection of local anesthetic without steroid?
Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging	1–2 provocation tests of SIJ positive	Spondyloarthritis	Intra-articular SIJ injection of steroid alone?
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 pelvis 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?
Normal imaging of the lumbar spine and pelvis	Provocation tests of SIJ negative	History of pelvic trauma	Intra-articular SIJ injection of local anesthetic without steroid?
Normal imaging of the lumbar spine and degenerative SIJ findings on pelvic imaging	1–2 provocation tests of SIJ positive	Spondyloarthritis	Intra-articular SIJ injection of steroid alone?
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 pelvis 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?
	≥50%		≥50%	Intra-articular SIJ injection of local anesthetic without steroid?
	≥75%		≥75%	Intra-articular SIJ injection of steroid alone?
	100%		100%	Lateral branch blocks?
Local anesthetic with steroid	<50%	Local anesthetic with steroid	<50%	
	≥50%		≥50%	
	≥75%		≥75%	
	100%		100%	
Local anesthetic	<50%	Local anesthetic	None	
	≥50%			
	≥75%			
	100%			
Local anesthetic with steroid	<50%	Local anesthetic with steroid	None	
	≥50%			
	≥75%			
	100%			

SIJ = sacroiliac joint.

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

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

SIJ = sacroiliac joint.

5. Lateral Branch Radiofrequency Neurotomy

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

Indications				Procedure
First Diagnostic Block		Second Diagnostic Block		
Site	Relief	Site	Relief	Duration of Symptoms
None		None		Less than 2 weeks
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
		Sacroiliac joint	<50%	
		Lateral branches	≥50%	
			≥75%	
			100%	

SIJ = sacroiliac joint.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Degenerative changes on imaging are findings that may be related to an aging spine or joint that may or may not be symptomatic, including osteophytes, joint 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).

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

ASIS = anterior superior iliac spine; SI = sacroiliac

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

ASIS = anterior superior iliac spine; SI = sacroiliac

Hip Provocation Tests (Physical Exam Findings)

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

ASIS = anterior superior iliac spine; SI = sacroiliac.

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