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Dear Drs. Berman, Loveless, and Sandler:

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

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

Significant relief of neck and back pain, improved quality of life, with restoration of function and return to work, as well as decreased utilization of other healthcare resources is an outcome that should be readily available to patients covered by Medicare. When facet interventions are performed in a disciplined, responsible manner, they achieve outcomes that are clinically, socially, and economically worthwhile [1,2].

MEDIAL BRANCH PROCEDURES

Medial branch thermal radiofrequency neurotomy (MBTRFN) is a validated treatment for facet joint pain. Long-term follow-up demonstrates that treatment effects are durable and reproducible if symptoms return.[3-7] Several systematic reviews have been published that address the body of evidence related to cervical and lumbar medial branch radiofrequency neurotomy.[3-6,7,] The quality of reviews vary, and we are highlighting significant issues with one high profile Cochrane review in order to illustrate the importance of appreciating technical aspects of the procedures and the importance of patient selection criteria.[7]

A 2015 Cochrane systematic review by Maas *et al* poorly serves the needs of payers and patients because it does not consider correct performance or appropriate patient selection for MBTRFN.[7] While such reports apply the basic requirements of systematic reviews, their depiction of the evidence is flawed due to lack of insight into these critical clinical practice parameters inherent to the procedures being assessed. The literature on MBTRFN must be meticulously stratified by technique, selection, and outcome.

Such a rigorous assessment of the evidence was accomplished in several systematic reviews.[3-6] Two of these reviews present the outcomes reported in the literature, stratified by technique and selection criteria, and conclude that effectiveness differs according to how patients are selected and how MBRFN is performed.[4,6] The use of single blocks for selection and perpendicular MBRFN technique results in inferior outcomes that may not be greater than sham treatments. In

comparison, superior outcomes are evident with the use of two blocks for selection and a parallel MBRFN technique.

For a variety of reasons, practitioners use different techniques (*e.g.* MBTRFN, pulsed RF), yet call their procedures by the same name. These procedures are not the same and must be assessed separately. Likewise, different clinical conditions result in different targets (*e.g.* medial branch nerves, dorsal root ganglion, sacroiliac joint) and must be assessed separately. Hereafter, our comments focus solely on evidence addressing MBTRFN technique, selection, and outcome.

Technique

For MBTRFN to have face validity and be capable of achieving the desired outcome, a thermal lesion must be made of sufficient size to cause ablation of a segment of the target nerve. The lesion size, which is influenced by active tip length, cannula diameter, temperature, and lesion time, should be made as large as possible.[8,9] Next, the electrode must be accurately placed for the resulting thermal lesion to optimally capture the target nerve. Basic science studies indicate that lesions from perpendicular electrode placements for MBTRFN either fail to reach the target nerve or capture only a small segment, while lesions from parallel electrode placements reliably capture the target nerve and do so along a substantial length of the nerve.[1,10-12] Thus, the orientation of the electrode is pivotal to clinical outcome, with perpendicular placements expected to have lower success rates and shorter durations of effect compared to parallel placements with greater success rates for longer periods. Indeed, this is borne out in the literature.

This issue is best illustrated by examining the larger evidence base available for lumbar MBRFN (LMBTRFN). Several RCTs do not qualify as providing evidence of efficacy because their active treatment arm lacked face validity by using the insufficient perpendicular technique.[13-16] The highly publicized randomized controlled trials by Juch *et al*[13] were irredeemably flawed by study design, patient selection, procedural technique, and data analysis.[17-22] The study employed small-gauge electrodes, which generated small lesions. The published images demonstrated that the electrode placements were perpendicular and lateral to the target nerves, and the lesions made by the electrodes would fail to reach the nerves. Censoring these studies leaves only those of Nath 2008, Tekin 2007, and van Kleef 1999 eligible to provide evidence related to the efficacy of LMBTRFN.[23-25] These three studies, taken together, provide evidence of significantly beneficial outcomes for patients in terms of pain relief, functional improvement, decreased consumption of analgesics, and improved overall quality of life.

Selection

Sufficient pain relief following appropriately performed diagnostic medial branch nerve blocks determines patient selection for MBTRFN. Dual comparative medial branch blocks employ two local anesthetics with different durations of action, administered at two different sessions. Patients who obtain relief consistent with the different durations of action of the local anesthetics are considered positive. Dual comparative blocks are advocated as a means of identifying true-positive cases and excluding placebo responders and have been shown to have a sensitivity of 100% and a specificity of 65%.[26]

Cervical MBTRFN

Evidence from high quality systematic reviews supports reliance on dual diagnostic blocks with 100% relief of the index pain to select patients for the procedure.[3,4]

- More than 60% of patients selected based upon 100% relief of the index pain were pain free at 6 months and nearly 40% were pain free at 1 year with restoration of activities of daily living and no need for other health care for neck pain.

- There is no admissible evidence that patients selected based on response to intra-articular blocks or single medial branch blocks will achieve this rate of good outcomes after cervical MBTRFN (CMBTRFN).

For patients selected using dual comparative blocks with ≥50% or ≥75% relief of pain: 68% achieve ≥50% relief of pain, 43% achieve ≥80% relief, and 29% achieve complete relief. Thus, patients also see significant benefits even with less restrictive criteria for selection.

Lumbar MBTRFN
There are different schools of thought within the interventional pain community about whether to rely on a single block with 50% relief or require dual blocks with 80% relief to select patients for LMBTRFN.

- 50% Relief, Single Lumbar Medial Branch Block

A recently published multisociety consensus guideline advocates for use of at least 50% relief from a single diagnostic block as an appropriate threshold to select patients for LMBTRFN.[27] This recommendation prioritizes the optimization of the number of patients who are provided pain relief over the optimization of the treatment success rate. While evidence shows the treatment success rate of LMBTRFN is higher using the more stringent criteria of 80% relief from dual blocks, it also shows that some patients who do not meet this criteria but who do achieve at least 50% relief from a single block can obtain some degree of relief from LMBTRFN. A meta-analysis found that 57% (95% CI: 52-62%) of patients selected on the basis of 50% relief from a single medial branch block and treated with electrodes placed parallel to the target nerve achieved at least 50% relief of pain at 6 months.[6] At times, this treatment may be the best available option for patients who have failed more conservative treatments and who wish to avoid the alternative treatments available to them (e.g. opioids, surgery).

- 80% Relief, Dual Medial Branch Blocks

Conversely 50% pain relief from a single diagnostic block is viewed by some as an unacceptable selection method due to high false-positive rates. Specifically, the single block false-positive rate is between 25-45%, and this is significantly reduced by performance of a second comparative block.[28-35] Thus, the recommendation to select patients for LMBTRFN using dual blocks with a higher pain relief threshold prioritizes treatment success in the smaller number of selected patients. Accordingly, the two benchmark studies of LMBTRFN used 80% to 100% relief thresholds following dual comparative local anesthetic blocks and a parallel treatment technique[36,37] – the selection criteria recommended by current LCDs and supported by many physicians and societies. Both studies achieved the best results heretofore reported in the literature. The first study reported 60% of patients maintaining at least 80% relief for 12 months.[36] The second study reported complete relief of pain for at least 6 months in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 15 months per treatment.[37] An impressive 55-60% of patients experience at least 80% pain relief.

Regardless of whether patients are selected based on 50% relief from a single block or 80% relief from dual blocks, LMBTRFN results in significant pain relief, reduced disability, and improved quality of life for patients suffering from chronic low back pain.

Outcomes
The outcomes of MBTRFN should be quantified in several domains:

- degree of relief that constitutes success;
- success rate: the proportion of patients who achieve a successful outcome;
- duration of relief;
- corroboration of relief by improvements in critical domains such as restoration of function, return to work, and use of other health care.

Based on the most rigorous studies using appropriate diagnostic techniques to select patients and using optimal treatment techniques of MBTRFN:

- Over 60% of patients treated with CMBTRFN can expect to be pain free at 1 year with restoration of activities of daily living and no need for other health care for neck pain. [3,4,38]
- Over 50% of patients treated with LMBTRFN can expect to achieve 80-100% relief of pain,[36,37] accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their back pain, for a median duration of 12-15 months, with an interquartile range of 10-28 months.[37]
- In the event of recurrence of pain, complete relief can be reinstated by repeating the treatment.[37,38]

Medicare Administrative Contractors should continue to support practices that achieve such outcomes and ensure that they remain available to Medicare patients.

FACET JOINT INJECTIONS

The North American Spine Society's Facet Joint Interventions Coverage Policy Recommendations (attached) provide a comprehensive overview of the evidence and recommendations for appropriate use of diagnostic and therapeutic cervical and lumbar facet joint injections.[39] Key recommendations are summarized below:

- Intraarticular facet joint blocks should not be routinely used over medial branch blocks to identify appropriate candidates for MBTRFN as they have less supporting evidence for predicting treatment response. They may be used when medial branch blocks cannot be performed.
- Therapeutic facet joint injections can be used to provide short- and mid-term pain relief[40-42], and are particularly useful in relieving pain attributable to facet synovial cysts[43-50] and acute facet joint inflammation[51,52]. They can also be used when patients have contraindications to MBTRFN.
- Therapeutic facet joint injections may be repeated if the first injection results in significant pain relief (>50%) for at least 3 months.
- A maximum of 5 facet injection sessions inclusive of medial branch blocks, intraarticular injections, facet cyst rupture, and RF ablations may be performed per rolling 12-month year in the cervical/thoracic spine and 5 in the lumbar spine.
- Facet joint injection/access is necessary for interventional treatment (rupture, fenestration) of synovial cysts arising from the facet joint.

Summary of Key Recommendations

- MBTRFN is an effective treatment for chronic neck and back pain in appropriately selected patients and should be a covered service for Medicare patients
- MBTRFN can be repeated in patients who achieve at least a 50% reduction in pain for ≥6 months.
- Selection of patients for MBTRFN is performed with medial branch blocks.
  We recommend:

- In the cervical spine, continued coverage as recommended in existing LCDs, (*i.e.* patients must achieve ≥80% reduction in pain on dual diagnostic blocks).
- In the lumbar spine, given the differing views amongst physicians and societies about appropriate selection criteria, we recommend that the Medicare Administrative Contractors carefully consider whether the criteria be:
  - At least 80% reduction in pain from dual medial branch blocks, which has been shown to result in the highest percentage of patients achieving positive outcomes;

    - or -
  - At least 50% reduction in pain from a single medial branch block, which makes this treatment available to more patients, thus providing relief to a greater number of patients overall.

- Therapeutic facet injections should be available to Medicare patients as they may provide short- or mid-term pain relief and are useful in treating painful facet synovial cysts and acute facet joint inflammation.

The undersigned societies appreciate the opportunity to provide these comments. The MPW societies would welcome the opportunity to again work with the Medicare Administrative Contractors to revise the coverage criteria included in the LCDs to ensure appropriate access to facet interventions for Medicare patients. If you have any questions or wish to discuss any of our suggestions, please contact Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Association of Neurological Surgeons

American Academy of Pain Medicine

American Academy of Physical Medicine and Rehabilitation

American Society of Anesthesiologists

American Society of Neuroradiology

American Society of Spine Radiology

California Society of Anesthesiologists

Congress of Neurological Surgeons

North American Neuromodulation Society

North American Spine Society

Society of Interventional Radiology

Spine Intervention Society

Attachments:

- Engel A, Rappard G, King W, Kennedy DJ. The effectiveness and risks of fluoroscopically-guided cervical medial branch thermal radiofrequency neurotomy: A systematic review with comprehensive analysis of the published data. Pain Med 2016;17:658-69
- Schneider BJ, Doan L, Maes MK, Martinez KR, Gonzalez Cota A, Bogduk N. Systematic review of the effectiveness of lumbar medial branch thermal radiofrequency neurotomy, stratified for diagnostic methods and procedural technique. Pain Med 2020 Feb 10. [Epub ahead of print]
- Multisociety Statement on *Effect of Radiofrequency Denervation on Pain Intensity Among Patients with Chronic Low Back Pain: The Mint Randomized Clinical Trials* by Juch *et al.* November 21, 2017.
- Cohen SP, Bhaskar A, Bhatia A, Buvanendran A, Deer T, Garg S, Hooten WM, Hurley RW, Kennedy DJ, McLean BC, Moon JY, Narouze S, Pangarkar S, Provenzano DA, Rauck R, Sitzman BT, Smuck M, van Zundert J, Vorenkamp K, Wallace MS, Zhao Z. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med 2020 Apr 3. [Epub ahead of print]
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OXFORD

Review Article

The Effectiveness and Risks of Fluoroscopically-Guided Cervical Medial Branch Thermal Radiofrequency Neurotomy: A Systematic Review with Comprehensive Analysis of the Published Data

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Conflicts of interest: None of the authors has any financial conflicts of interest to disclose.

Abstract

Objective. To determine the effectiveness and risks of fluoroscopically-guided cervical medial branch thermal radiofrequency neurotomy (CMBTRFN) for treating chronic neck pain of zygapophysial joint origin.

Design. Systematic review of the literature with comprehensive analysis of the published data.

Interventions. Four reviewers formally trained in evidence-based medicine searched the literature on CMBTRFN. Each assessed the methodologies of studies found and appraised the quality of evidence presented.

Outcome Measures. The primary outcomes assessed were 100% relief of pain 6 and 12 months after treatment. Other outcomes were noted if reported. The evidence was evaluated in accordance with the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system.

Results. The searches yielded eight primary publications on the effectiveness of the procedure. The evidence shows a majority of patients were pain free at 6 months and over a third were pain free at 1 year. The number needed to treat for complete pain relief at 6 months is 2. The evidence of effectiveness is of high quality according to the GRADE system. Twelve papers were found reporting unwanted effects, most of which are minor and temporary. No serious complications have ever been reported from procedures performed according to the published guidelines. The evidence of risks is of low quality according to the GRADE system.

Conclusions. If performed as described in the International Spine Intervention Society Guidelines, fluoroscopically-guided CMBTRFN is effective for abolishing zygapophysial joint pain and carries only minor risks.

Key Words. Cervical; Zygapophysial; Facet; Medial; Branch; Radiofrequency; Neurotomy

Introduction

Cervical medial branch thermal radiofrequency neurotomy (CMBTRFN) is a minimally invasive percutaneous procedure for the treatment of chronic neck pain and cervicogenic headache. It uses an electric current, alternating at the frequency of radio waves, to coagulate the nerves from cervical zygapophysial (Z) joints, and thereby interrupt nociceptive transmission from these joints. The target nerves are the medial branches of one more of the cervical dorsal rami, or the third occipital nerve, which have previously been shown to the responsible for

mediating the patient's pain. A specialized electrode is placed immediately adjacent to, and parallel to, the target nerve. A radiofrequency generator delivers the alternating current to the body through a dispersion pad. The resulting electric field concentrates near the tip of the electrode, and heats the tissues surrounding the tip, thereby coagulating the adjacent nerve. The process is repeated to produce multiple radiofrequency (RF) lesions along each target nerve. The nerves are treated one at a time, and a maximum of three nerves treated in any one application of the procedure.

Critical to correct interpretation of the evidence on CMBTRFN is understanding that there are various other procedures with similar names, which are often mistakenly lumped together. For the purposes of this review, CMBTRFN is defined as the procedure described in the practice guidelines published by the International Spine Intervention Society in book form [1] and in antecedent journal articles [2,3].

The history of RF treatments goes back more than 50 years. Radiofrequency neurotomy (RFN) was first described as a treatment for pain in 1960, in a paper on relief of intractable pain by percutaneous anterolateral cordotomy [4]. RFN was subsequently applied as a treatment for trigeminal neuralgia in 1967 [5]. In 1970s and 1980s, RFN began to be used to treat back pain and neck pain.

For the treatment of back pain Shealy [6] and Schaerer [7,8] described thermal RF techniques aimed at the center of the target joint. Sluijter [9] wrote about techniques aimed at the dorsal ramus and the dorsal root ganglion. Bogduk and Long [10] demonstrated that the techniques of Shealy and Schaerer were not anatomically valid, and corrected the technique to target the lumbar medial branches accurately [11].

For the treatment of neck pain, a review of the literature [12] highlighted the limitations of earlier studies and outlined a sound anatomical basis for cervical medial branch neurotomy.

Subsequent studies validated the procedure [3,4,13,14], and became the basis for the guidelines of the International Spine Intervention Society (the Society) [1].

However, other forms of RF treatment, many of them not anatomically valid, remain in use by some; and those procedures are often confused with CMBTRFN as defined by the Society. These other procedures include those that purport to place effective thermal RF lesions over target nerves but are performed in ways that do not achieve the purpose, and procedures with similar-sounding names such as "pulsed RF neurotomy" in which radiofrequency currents are used to produce heat of much less intensity from electrodes placed quite differently. Such procedures are outside the scope of this review.

The Society's description of CMBTRFN includes the indications for the procedure [1]. Specifically, it should be done only for Z joint pain diagnosed definitively by analgesic responses to comparative medial branch blocks (MBBs) or third occipital nerve blocks (TONBs). The validity of these tests has been demonstrated in three domains: face validity, construct validity, and predictive validity. Their face validity, or target-specificity, was demonstrated in a study showing the spread of the injectate is limited to the location of the target nerve [15]. The construct validity of MBBs depends on the extent to which positive or negative block results show that the joint tested is, or is not, a pain source. Single cervical MBBs have a false-positive rate of 27% [16]. This liability of false-positive results is overcome by undertaking comparative MBBs, i.e., performing two blocks on separate occasions using different local anesthetics and comparing the durations of response to the durations of action of the agents injected [17]. The addition of a placebo control provides even greater diagnostic confidence, but the utility of comparative cervical MBBs has been shown to be satisfactory for clinical purposes [18]. Thus, in this review, "comparative blocks" include dual blocks performed with or without the addition of placebo controls. Predictive validity refers to the value of diagnostic test results in predicting responses to treatment. The predictive validity of cervical MBBs was established in a study which showed positive and concordant responses to comparative MBBs accurately predicted successful outcomes when those joints were treated by RFN [2]. Thus, the diagnostic validity of comparative cervical MBBs has been demonstrated in all three domains.

Other methods of patient selection for RF treatment have been described, including tenderness to palpation on clinical examination [19,20] and analgesic response to joint blockade by intra-articular injection of local anesthetic [11] or dorsal ramus blockade [21]. None of these methods of patient selection have been validated by sound evidence, and in particular, clinical examination has been shown to be invalid [22].

Medical imaging modalities have been investigated as a means of diagnosing cervical joint pain, but none has been validated. Radiographic appearances simply do not correlate with cervical pain. Studies have shown that plain X-ray findings [23–27], computerized tomography (CT) findings [23,26], even when single photon emission CT is used [28], and the findings of magnetic resonance imaging [26,29–33] are not useful for diagnosing painful cervical joints. No imaging modality provides valid diagnosis of a painful cervical joint.

Accordingly, positive results of comparative MBBs or TONBs constitute the only validated methods for diagnosis of cervical Z joint pain and, therefore, for selecting patients for CMBTRFN [17,34]. Procedures done without those indications are outside the scope of this review.

The importance of the effectiveness of CMBTRFN is underlined by the prevalence of cervical Z joint pain. Studies have shown cervical Z joints are the most

common sources of pain associated with motor vehicle accidents which cause "whiplash" injuries [35–37]. Studies using comparative MBBs and TONBs show cervical Z joint pain accounts for 60% (CI_{95} 46–73%) of chronic neck pain after whiplash [37], and when headache is the dominant symptom after whiplash, pain referred from the C2-3 Z joint (third occipital headache) accounts for 53% (CI_{95} 37–68%) of cases [35]. Cervical Z joint pain also has a high prevalence in nontraumatic cases of chronic neck pain [38]. These data suggest cervical Z joint impairment is a common cause of chronic neck pain and cervicogenic headache; so, CMBTRFN is a treatment that is commonly indicated. This review identifies and appraises the published evidence on its effectiveness and its risks.

Methods

Four investigators, who all have formal training in evidence-based medicine, searched the scientific literature independently for publications on the effectiveness of fluoroscopically-guided CMBTRFN. Initially they each conducted digital searches using the search engine Ovid to explore the databases Embase, Medline, and EBM Reviews, using the keywords cervical, zygapophysial, facet, medial, branch, radiofrequency, and neurotomy. The searches encompassed all scientific papers published until March 2015 but excluded were nonhuman studies, conference abstracts and case reports, unless they were reports of complications. When suitable papers were retrieved, the references of each were perused for relevant citations that might not have been identified by the database searches.

The primary publications found were classified into three types: observational studies (simply describing outcomes after the use of an intervention), pragmatic studies (comparing outcomes after use of an intervention with outcomes after use of another intervention expected to have a therapeutic effect), and explanatory studies (comparing outcomes after use of an intervention with outcomes after use of another intervention not expected to have a therapeutic effect). The primary papers on effectiveness of fluoroscopically-guided CMBTRFN were appraised by each of the investigators independently, using an instrument developed by the International Spine Intervention Society's Standards Division to facilitate reliable assessment of studies of therapeutic effectiveness. The investigators then discussed the studies to reach consensus on the value of each paper's contribution to the published evidence of the effectiveness of CMBTRFN.

Categorical data were sought as the preferred evidence of effectiveness because they reflect binary outcomes (patients achieving or not achieving a successful result). Such data, expressed as success rates, can be collated to produce a body of evidence of effectiveness based on outcomes for specific patients [39]. In this review, the primary outcome measures sought were success rates for complete relief of pain at 6 and 12 months after treatment. The results of studies that produced categorical data for individual patients were tabulated.

The data from all the studies following the Society's guidelines were appraised and the resultant body of evidence was evaluated using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of appraisal to determine the quality of the evidence of the effectiveness of CMBTRFN.

Using the same methodology, the published data on the risks of CMBTRFN were evaluated using the GRADE system. The same keywords were used, and safety, complications, and unwanted effects were added. The quality of the published evidence of effectiveness and the published evidence of risks were then both taken into account and conclusions were drawn in accordance with the GRADE system about the strength of recommendations for use of CMBTRFN based on all published data on the procedure.

Results

The literature searches yielded eight primary papers that reported data on effectiveness. Of the eight reports, six were observational studies and two were explanatory studies. Also found were 12 papers reporting complications of cervical RFN, but only four of them related to CMBTRFN as defined. Another 76 publications were identified but were not included in this review because the patients were selected by invalid methods, the papers contained no primary data, or the papers were letters or reviews of the literature.

Effectiveness

Observational Studies

The first data on CMBTRFN using dual comparative blocks with complete relief for patient selection was an observational pilot study [12]. Nineteen patients and 21 joints were treated. The data were divided into outcomes of RF treatment of the third occipital nerve (TON) for chronic pain from the C2-3 Z joint (n = 10 patients) and treatment of the C5, C6, and C7 medial branches for chronic pain from the C5-6 and C6-7 Z joints (n = 10 patients); one patient had the C2-3, C5-6, and C6-7 joints treated. As the third occipital neurotomies were not done in accordance with the Society's current guidelines, their results were not suitable for inclusion in this review. After CMBTRFN for lower cervical Z joint pain, 7/10 patients (70% [CI_{95} 42–98%]) were pain free at 6 months and 4/10 patients (40% [CI_{95} 10–70%]) were pain free at 1 year. The authors of this pilot study concluded that the results justified progress to a randomized controlled trial of CMBTRFN for lower cervical Z joint pain.

Five more observational studies of the effectiveness of CMBTRFN were published between 1998 and 2012 [3,13,14,40,41]. In all of these studies, patients were

selected based on complete relief of chronic neck pain and/or headache by each of two CMBBs or TONBs, and were treated by CMBTRFN performed strictly in accordance with the Society's guidelines. All patients were followed up assiduously, and their outcomes were recorded to determine the success rates of the treatment.

The first and second of these studies were from the same group of investigators and addressed different aspects of CMBTRFN when performed on the same group of 28 patients with chronic neck pain stemming from Z joints between the C3-4 and C6-7 levels [13,14]. At review 6 months after treatment, 16/28 (57% [CI_{95} 39–75%]) were pain free. After 12 months, 10/28 (36% [CI_{95} 18–54%]) were pain free. The median duration of relief after a first procedure was 219 days when failures were included; but for patients who had a successful outcome, the median duration of relief was 422 days. An important finding was that when the effect wore off and the pain recurred, pain relief could be reinstated by repeat CMBTRFN. Another important finding was that the litigation status of patients did not influence outcomes.

A study published in 2003 addressed the treatment of chronic upper neck pain and cervicogenic headache stemming from C2-3 Z joints [3]. This study described a new TON treatment procedure, which is now the basis for the Society's guidelines, and was designed to overcome the technical problems identified in an earlier pilot study [12]. Of the 49 patients included, 32 (65% [CI_{95} 52–78%]) were pain free at the 6 month review and 10 (20% [CI_{95} 9–31%]) were pain free after 12 months.

Two studies published in 2005 and 2012 investigated the effectiveness of CMBTRFN when applied in community settings to treat chronic pain from any of the cervical Z joints. In the earlier study involving 35 patients, 16 (46% [CI_{95} 29–63%]) were pain free at 6 months and nine (26% [CI_{95} 11–41%]) were pain free at 12 months [40]. In the later study involving 104 patients, 71 (68% [CI_{95} 59–77%]) were pain free at 6 months and 53 (51% [CI_{95} 41–61%]) were pain free at 12 months [41].

Explanatory Studies

In 1996, Lord et al. published a double blind explanatory study of the effectiveness of CMBTRFN performed on patients with chronic cervical Z joint pain diagnosed by comparative, placebo-controlled MBBs [2]. At 6 months after CMBTRFN, 7/12 (58% [CI_{95} 30–86%]) patients in the active treatment group were pain free, while 1/12 (8% [CI_{95} 0–23%]) patients in the placebo group was pain-free. These confidence intervals do not overlap, demonstrating that the results of CMBTRFN are not due to a placebo effect. These data also show the number needed to treat (NNT) by CMBTRFN for complete pain relief is 2.

The following year, the same group of investigators published another explanatory study of the effect of CMBTRFN on psychological distress [42]. The results were measured only 3 months after treatment, so are not suitable for inclusion with the other data in this review. Patients in the active treatment group who experienced complete relief of pain also had resolution of associated psychological symptoms.

The categorical data on the effectiveness of CMBTRFN after 6 months and 12 months are tabulated below in Tables 1 and 2.

If the data in each of Tables 1 and 2 are added, they show that when patients were treated by CMBTRFN after diagnosis by at least dual comparative blocks with 100% relief, 149/238 patients (63% [CI_{95} 57–69%]) were pain free at 6 months and 86/226 (38% [CI_{95} 32–44%]) were pain free at 1 year.

GRADE Evaluation of Evidence of Effectiveness

The two explanatory studies [2,42] start as high quality evidence and there is no reason to downgrade them. The six observational studies start as low quality evidence and there is no reason to downgrade any of them, but they should be upgraded for magnitude of effect and a dose response curve [43]. As the confidence intervals of the explanatory studies overlapped the confidence intervals of the observational studies, and data from the treated groups did not overlap the data from the placebo groups, the observational studies can be upgraded. In addition to the large magnitude of effect, there was a clear dose response relationship: when RF treatment effects wear off, complete pain relief can be reinstated with repeat treatment.

Thus, the evidence of the effectiveness of CMBTRFN for producing total relief of neck pain or cervicogenic headache (when patients are selected by CMBBs) is of high quality: the true effect is likely to be close to that shown by the published data, and further research is unlikely to change the conclusions presented.

Risks

The literature searches produced four papers that described risks associated with CMBTRFN as defined by the Society's criteria. Those risks are summarized in Table 3.

The first study to mention risks of CMBTRFN was published in 1995 [12]. The authors did not provide specific data, but noted that after CMBTRFN procedures patients often experienced temporary dizziness, giddiness, and ataxia due to effects on nerve fibers involved in proprioception and balance. They also noted most patients needed analgesic medications for postoperative pain for some days after a CMBTRFN procedure. The paper also mentioned several theoretical risks of cervical RFN but they remain theoretical, as they have never

Table 1 Reported rates of success (defined as abolition of pain) 6 months after CMBTRFN of patients selected by analgesic responses to comparative medial branch blocks

Study	Design	Levels	Pain Completely Relieved	
Lord [1995]	Observational	C5-7	7/10	70% (CI_{95} 42–98%)
Lord [1996]	Explanatory	C3-7	7/12	58% (CI_{95} 30–86%)
McDonald [1999]	Observational	C3-7	16/28	57% (CI_{95} 39–75%)
Govind [2003]	Observational	C2-3	32/49	65% (CI_{95} 52–78%)
Barnsley [2005]	Observational	C2-7	16/35	46% (CI_{95} 29–63%)
MacVicar [2012]	Observational	C2-7	71/104	68% (CI_{95} 59–77%)

Table 2 Reported rates of success (defined as abolition of pain) 12 months after CMBTRFN of patients selected by analgesic responses to comparative medial branch blocks

Study	Design	Levels	Pain Completely Relieved	
Lord [1995]	Observational	C5-7	4/10	40% (CI_{95} 10–70%)
McDonald [1999]	Observational	C3-7	10/28	36% (CI_{95} 18–54%)
Govind [2003]	Observational	C2-3	10/49	20% (CI_{95} 9–31%)
Barnsley [2005]	Observational	C2-7	9/35	26% (CI_{95} 11–41%)
MacVicar [2012]	Observational	C2-7	53/104	51% (CI_{95} 41–61%)

Table 3 Risks and complications of CMBTRFN procedures recorded in the literature, their prevalence (95% confidence intervals), and the references in which they were first documented

Risks	Levels	Frequencies	Notes	References
Radiation risks	C2-7	100%	Minimal	Lord [1998]
Postprocedural pain	C2-7	98% (95–100%)	Temporary	Lord [1998]
Cutaneous numbness	C2-3	97% (93–100%)	Enduring	Govind [2003]
	C2-7	47% (36–58%)		Lord [1998]
Dizziness and ataxia	C2-3	95% (90–100%)	Temporary	Govind [2003]
	C2-7	23% (14–32%)		Lord [1998]
Dysesthesias	C2-3	55% (43–67%)	Temporary	Govind [2003]
	C2-7	30% (20–40%)		Lord [1998]
Pruritis	C2-3	9% (2–16%)	Temporary	Govind [2003]
Postprocedural infection	C2-7	3% (0–9%)	Temporary; one case	Barnsley [2005]
Vasovagal syncope	C2-7	2% (0–5%)	Temporary	Lord [1998]
Neuritis	C2-7	2% (0–5%)	Temporary to enduring	Lord [1998]
Dermoid cyst	C2-7	1% (0–3%)	Enduring: one case	Lord [1998]
Köbner's phenomenon	C2-7	1% (0–3%)	Enduring: one case	Lord [1998]

been reported in the literature as having actually occurred.

Another study published in 1998 reported rates of unwanted events with CMBTRFN of the C3-7 Z joints [13]. It was an audit of 83 treatments completed over 5.5 years with meticulous follow-up of patients' outcomes. No serious complications occurred in the cohort. Less severe side-effects that were noted included postoperative pain in 81/83 or 98% (CI_{95} 95–100%), dysesthesias in 25/83 or 30% (CI_{95} 20–40%), cutaneous numbness in 39/83 or 47% (CI_{95} 36–58%), dizziness and ataxia in 19/83 or 23% (CI_{95} 14–32%), vasovagal syncope (or presyncope) and postprocedural neuritis were both reported in 2/83 or 2% (CI_{95} 0–5%), while development of a dermoid cyst and Köbner's

phenomenon (psoriasis at the site of puncture) were each reported in 1/83 or 1% (CI_{95} 0–3%). Only one study has ever reported a postprocedural infection: Barnsley noted that, in one patient from a series of 47 CMBTRFN procedures performed on 35 patients, the infection was superficial and with oral antibiotics it resolved without sequelae [40].

Other theoretical risks not manifest in these early study cohorts but discussed in the papers as potential hazards included radiation exposure, allergic reactions, bruising, ground electrode burns, neuroma, anesthetica dolorosa, and risks associated with implanted electrical devices such as cardiac pacemakers.

Side-effects of CMBTRFN of the TON for C2-3 Z joint pain have also been reported in observational studies. Govind was the first to report rates of unwanted events in 2003 [3]. Numbness in a small area behind the ear (the area supplied by the TON) was reported afterward in 63/65 or 97% (CI_{95} 93–100%) of the procedures done. Temporary ataxia (lasting up to a day or so) was reported after 62/65 or 95% (CI_{95} 90–100%) of the procedures. Dysesthesias, ranging from hypoesthesia to hypersensitivity to touch, occurred after 36/65 or 55% (CI_{95} 43–67%) of procedures; the effects lasted for 1–2 weeks in most patients affected, but for 4 weeks in one case; no case required treatment. Itch occurred after 6/65 or 9% (CI_{95} 2–16%) of treatments; it too was of short duration.

The unwanted effects and risks of CMBTRFN reported in the literature are summarized below in Table 3.

GRADE Evaluation of Evidence of Risks

When assessing the quality of the evidence on the risks of CMBTRFN in accordance with the GRADE system, it is noted that the published evidence consists of four observational studies. Accordingly, the body of evidence is of low quality: our confidence in the effect estimate is limited and the true effect may be substantially different from the estimate of the effect [43].

Discussion

Following the paradigm established by the Standards Division of the International Spine Intervention Society [44–47], this review is comprehensive: it includes the whole body of peer-reviewed literature producing categorical evidence and that body of evidence has been appraised using GRADE. If only randomized controlled trials had been studied, sound data from rigorous observational studies would have been ignored. This review does not include other techniques or selection criteria that have not been validated.

The evidence shows CMBTRFN results in 63% (CI_{95} 57–69%) of patients being pain free at 6 months and 38% (CI_{95} 32–44%) pain free at 1 year. It has also been shown to allow patients to return to all activities previously inhibited by pain, including work [48].

This effectiveness is absolutely dependent on the procedure being performed in accordance with the published guidelines [1], and in particular, on patients being selected following positive and concordant responses to dual, comparative, diagnostic blocks producing 100% relief (with or without additional placebo controls). The evidence for CMBTRFN cannot be generalized to RF procedures not performed in accordance with the guidelines; the effectiveness of such procedures is unknown.

The distinction between CMBTRFN performed according to guidelines and other types of RF treatment has not been recognized in previous reviews [49–51]. Those reviews included other types of RF treatment performed on patients selected in a variety of other ways, so it is not surprising that when results of such procedures are pooled with those of CMBTRFN performed in accordance with published guidelines, the overall picture is confusing and may be interpreted as showing RF treatments are ineffective. Some types of RF treatment undoubtedly are ineffective, but generalization is not justified. The reports of those previous reviews have given rise to misunderstanding of the effectiveness of CMBTRFN and have been used by some to disparage the procedure. The evidence of the current review counters that misunderstanding; it shows, unquestionably, that CMBTRFN is effective when performed in accordance with the Society's guidelines [1].

CMBTRFN is not a permanent cure for cervical Z joint pain. There is no intervention proven effective for restoring impaired spinal joints to their original condition. However, the actual impairments are usually very small and not of structural significance; their main effect is to cause chronic pain [24,25,52]. CMBTRFN abolishes the pain for long periods by denaturing the chemical components of nociceptive Aδ and C nerve fibers and preventing conduction through them. It does not destroy the target nerves. They remain intact anatomically and over time they recover; then the pain returns, although it can be abolished again by repeat treatment [3,13,40,41,53,54]. A major factor determining the duration of effect is the length of the target nerve coagulated through its full thickness in an RF treatment. The length of nerve coagulated is in turn influenced by variations in the neuroanatomy of the nerves, in particular, variations in their diameters and courses, and the sizes of lesions created in the procedure.

These factors are exemplified by the literature on third occipital headache. The initial results of thermal RFN for its treatment were disappointing [12]. The problem was that the TON is anatomically variable in both its size and its course. Anatomic studies showed the TON is generally larger than the other medial branch nerves, with a mean diameter of 1.5 ± 0.4 mm [55]. By comparison, the other medial branches have diameters ranging from

0.9 ± 0.3 mm (the C4 and C5) down to 0.5 ± 0.2 mm (the C3). In addition, the course of the TON has a wider range of anatomic locations than other medial branches [55]. These factors mean RF lesions placed over the TON have less chance of coagulating the full thickness of the nerve for a satisfactory length than do lesions at other levels. Knowledge of the anatomic variability led to development of a modified treatment technique, allowing for the variations by placing larger RF lesions over a wider range of positions. When that technique was used for thermal RFN of the TON, the treatment was shown to be as effective as CMBTRFN at other cervical levels [3].

The size of RF lesions is governed by the diameter (or gauge) of the RF electrode used to create them, the length of its active tip, the temperature it reaches, and the time the heat is applied by it. The effects of these factors on RF lesion size were addressed by Bogduk et al. in 1987 [56] and have been addressed again recently by Cosman et al. [57]. A 23 gauge SMK electrode with a 4 mm active tip heated to 80°C for 90 seconds produces an RF lesion averaging 3.9 mm wide and 5.9 mm long [13]; by comparison, a 16 gauge RRE electrode with a 6 mm active tip heated similarly creates an RF lesion averaging 9.2 mm wide and 10.5 mm long [57]. It is not hard to see why the 23 gauge SMK electrode used in the first TON study [12] was less effective than the 16 gauge RRE electrode used in the second [3]. The data show that a 16-gauge electrode is to be preferred for all CMBTRFN procedures.

The use of specific interventions for treatment of chronic pain is controversial in some quarters. Some practitioners apparently believe that when pain has been present for 3 months or more, central sensitization has occurred and that process is irreversible, so the pain will persist indefinitely. This belief is reflected in claims that chronic pain is a disease in its own right [58,59]. So-called "centralists" who hold that belief say attempts by what may be called "peripheralists" to treat nociceptive mechanisms of chronic pain are futile, and that chronic pain should be managed by "multidisciplinary" methods that are based largely on psychological techniques aimed at helping patients cope with the pain [60–62]. Such dichotomous views are unlikely to be consistent with the broad range of possibilities encompassed by medical science and are at odds with the biopsychosocial model of pain put forward by Engel [63] who suggested considering the psychological and social domains of pain in addition to, not instead of, its biomedical domain. The evidence of this review shows narrow "centralist" beliefs to be erroneous. When performed according to the Society's guidelines, CMBTRFN is an effective treatment for abolishing chronic pain, with an NNT of 2. It clearly reverses central sensitization and allows patients previously disabled by chronic neck pain or cervicogenic headache to resume life pain-free. The effect of RFN in countering central sensitization was demonstrated explicitly in a study published in 2014 [64]. Reversal of central sensitization is not unique to CMBTRFN: analogous abolition of chronic pain is a common outcome after hip or knee replacement surgery, and after many other treatments for painful conditions [65]. An explanatory study in 1997 [42] and a recent observational study [66] have shown that CMBTRFN also relieves psychological symptoms associated with chronic pain.

The risks and complications of CMBTRFN listed in Table 3 vary in frequency and most are minor, transient side-effects, like intraprocedural vasovagal syncope (which occurs rarely), postprocedural dysesthesia (which is relatively common), and postprocedural dizziness and ataxia (which are also relatively common). Given the prevalence of these complaints, it is prudent for patients to take precautions against falling and not drive motor vehicles until the effects have worn off. Such temporary effects are easily managed and are not likely to deter informed patients from undergoing the procedure.

Postprocedural pain occurs in virtually all cases. It varies from mild discomfort to more intense ache and lasts for varying periods of a day or so up to 2 weeks or even longer. Such pain should be relieved by analgesic medication and reassurance that it will settle.

So-called "neuritic" pain that occurs sometimes after CMBTRFN is generally more troublesome, but it varies in intensity. Two papers record neuritis, pruritis, and third occipital neuralgia as side-effects of CMBTRFN [3,13]. These symptoms are more commonly reported following CMBTRFN of the TON, probably due to its cutaneous innervation. The effects described are probably all on a spectrum ranging from minor irritation of a treated nerve to major inflammation causing neuralgia. They are usually of short duration, between 2 and 6 weeks, and as with other postprocedural pain, should be relieved by analgesic medication and reassurance that it will settle.

In addition to the published risks of CMBTRFN described in the Results section, there are reports in the literature of side-effects and complications of cervical RFN procedures done in ways that do not conform to the Society's guidelines. The authors felt some of those side-effects and complications should be mentioned in this review because, although never reported in association with CMBTRFN done in accordance with the Society's guidelines, they are things of which practitioners and patients considering CMBTRFN should be aware. They may be thought of as potential dangers of cervical RFN if it is done in ways that differ from that which the Society recommends.

A case of Horner's syndrome was reported as occurring after a C5-6-7 RFN procedure in 2014. The condition remitted after 36 hours with no long-term sequelae [67].

Neuritis causing third occipital neuralgia was reported as a complication in a substantial minority of patients who underwent RFN of the TON in a series published

first as a meeting abstract in 2011 [68] and later as a refereed paper [69]. The problem was reported in the later paper as occurring in 19% (CI_{95} 9–29%) of the 64 patients treated: that figure is at odds with the numbers of severe postprocedural nerve irritation pains reported in all other studies, which record such effects as uncommon or rare. There is no certain explanation for the high incidence of neuritic pain in this series of patients, but analysis of the technique reported in the article shows that it was not the technique described in the Society's guidelines. Contrary to the guidelines, multiple electrodes were inserted at the same time. Significantly, the radiograph reproduced as Figure 3 in the article to show the first electrode placement for TON lesioning has a substantial long-axis fault, so if it had been corrected for the parallax error, the electrode would have been seen to lie much higher or lower than the operator expected. The lesion generated by that electrode may have caused inflammation of either the C2 dorsal ramus or the C3 medial branch, neither of which is meant to be a target of the procedure. Also, the article describes an additional lesion being placed deliberately "at the waist of the articular pillar of C2," another position not described as a target site in the Society's protocol, and where a lesion is likely to irritate the C2 dorsal ramus causing lesser occipital neuralgia. All that can be said for certain is that the 19% incidence of "third occipital neuralgia" does not apply to CMBTRFN as described in the Society's guidelines.

An observational study of possible complications of cervical RFN focused on the theoretical risk of applied RF fields interfering with implanted electrical medical devices [70]. It was a retrospective review of 30 patients with implanted devices who underwent 68 RF procedures over a 5-year period. No complication had occurred and its authors concluded that RF treatment can be undertaken safely in such patients as long as precautions are observed. No other report has been published of an actual complication caused by such interference.

"Dropped head syndrome," postoperative kyphosis due to extensor muscle denervation, has been reported twice in reports of individual patients treated by cervical RFN at multiple levels [71,72]. In both cases, the effects were troublesome for the patients and required treatment by surgical fusion. These reports are disconcerting. The effect seems due to denervation of cervical extensor muscles, which raises the possibility that too many levels were treated. The Society's guidelines warn excessive denervation, so it seems such outcomes can be avoided by following the guidelines.

Two cases of serious neural and vascular injuries were described in a paper in 2008 that were known to its authors by way of medicolegal proceedings [73]. The first was a patient who developed a Brown-Séquard syndrome after RF neurotomy of a C3-4 Z joint; the intraoperative films showed that electrodes were placed medial to the target joint, passing between the laminae and entering the spinal cord. The procedure was performed under general anesthesia, so the patient could not report any symptoms of impending neurological injury. The second case involved spinal cord infarction after what was supposed to be RF neurotomy of a C2-3 Z joint; films showed an electrode lying in the C3-4 intervertebral foramen (not the C2-3 foramen) and placed too far anteriorly and medially. It seems a reinforcing radicular artery was coagulated in the C3-4 intervertebral foramen, producing infarction in the territory of the anterior spinal artery.

While serious complications of neural and vascular injuries must be recognized as risks of cervical RFN, it must be stressed that they have only been described after procedures done contrary to the published guidelines. The most important safety factor stipulated in those guidelines is that the procedure should not be done under general, anesthesia; local anesthesia is all that is required. Patients undergoing CMBTRFN must be awake and fully responsive so they can report the unusual sensations that will result from inaccurate electrode placement [1]. If an electrode is placed in an incorrect position during a procedure performed under general anesthesia, as in the two cases reported above [73], the unconscious patient cannot report an unusual sensation and nontarget structures such as the spinal cord or a reinforcing radicular artery may be lesioned inadvertently, with disastrous consequences. It is too late to recognize such serious errors when the patient is woken up after a procedure but they are totally avoidable, and indeed have never been reported, when CMBTRFN has been performed on conscious patients.

The incidence of serious complications like neural and vascular injury is unknown, but they are almost certainly much more common than the two cases reported in the literature. One of the current authors knows, through medicolegal processes, of three cases of cervical lateral ramus injury with serious neurological sequelae after RF procedures performed on unconscious patients. Other authors know of similar injuries too. Clearly there is a strong bias against publication of such outcomes [74]. One reason for the under-reporting is that their publication tends to be suppressed as conditions of litigation settlement. The potential for such complications should be recognized by all who undertake CMBTRFN, but reassurance can be had from knowing that no such serious complication has ever been reported after an RF procedure performed in accordance with the Society's guidelines.

The summary of the published evidence on risks is that if CMBTRFN is performed in accordance with the Society's guidelines, only minor and temporary side-effects are likely to occur and those effects are readily managed.

The published evidence on risks of CMBTRFN and similar procedures is of low quality according to the GRADE system. Readers must be careful not to confuse

"evidence of low quality" with "evidence of little significance" and perhaps go on to dismiss the risks of cervical RFN as of little concern. The evidence of risks is of low quality because it is based on observational studies and case reports. Few serious complications have been published, but the apparent publication bias, resulting in severe complications not being reported in journals, must be taken into account. Serious complications may occur if RF procedures are done in unorthodox ways, but they are extremely unlikely to occur if CMBTRFN is performed in accordance with the Society's guidelines.

Conclusions

In patients selected by comparative MBBs, fluoroscopically-guided CMBTRFN is effective for abolishing neck pain or cervicogenic headaches if done as described in the International Spine Intervention Society guidelines [1]. The procedure carries some risks, most of which are minor and temporary. Serious complications such as neural and vascular injury have been reported after cervical RFN, but they have only occurred when the Society's guidelines for the procedure have not been followed.

In accordance with the GRADE system, based on all published data on the procedure and taking into account the balance between desirable and undesirable effects, and the qualities of the evidence for each, the strength of recommendations is strong for use of CMBTRFN when the selection criteria include dual, comparative, MBBs, or placebo-controlled blocks producing 100% relief. The evidence of effectiveness of cervical RF neurotomy undertaken using any other selection criteria is unknown.

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Review Article

Systematic Review of the Effectiveness of Lumbar Medial Branch Thermal Radiofrequency Neurotomy, Stratified for Diagnostic Methods and Procedural Technique

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Abstract

Objective. To determine the effectiveness of lumbar medial branch thermal radiofrequency neurotomy based on different selection criteria and procedural techniques. **Design**. Comprehensive systematic review. **Methods**. A comprehensive literature search was conducted, and all authors screened and evaluated the studies. The Grades of Recommendation, Assessment, Development, and Evaluation system was used to assess all eligible studies. **Outcome Measures**. The primary outcome measure assessed was the success rate of the procedure, defined by varying degrees of pain relief following neurotomy. Data are stratified by number of diagnostic blocks and degree of pain relief, as well as procedural technique with perpendicular or parallel placement of electrodes. **Results**. Results varied by selection criteria and procedural technique. At six months, 26% of patients selected via single medial branch block with 50% pain relief and treated via perpendicular technique achieved at least 50% pain relief; 49% of patients selected via dual medial branch blocks with 50% pain relief and treated via parallel technique achieved at least 50% pain relief. The most rigorous patient selection and technique—two diagnostic medial branch blocks with 100% pain relief and parallel electrode placement—resulted in 56% of patients experiencing 100% relief of pain at six months. **Conclusions**. This comprehensive systematic review found differences in the effectiveness of lumbar medial branch radiofrequency neurotomy when studies were stratified by patient selection criteria and procedural technique. The best outcomes are achieved when patients are selected based on high degrees of pain relief from dual medial branch blocks with a technique employing parallel electrode placement.

Key Words: Lumbar; Zygapophysial Joint; Facet Joint; Medial Branch; Radiofrequency Neurotomy

Introduction

Not all back pain is the same. Some patients have pain that is mediated by medial branches of the lumbar dorsal rami [1–4]. The source of the pain is believed to lie in one or more of the lumbar zygapophysial joints that are innervated by the medial branches. The diagnosis is established if blocking particular medial branches temporarily relieves a patient's pain. It can then be treated by a procedure called lumbar medial branch (thermal) radiofrequency neurotomy (RFN). The paradigm of lumbar medial branch RFN is that if diagnostic medial branch blocks relieve the pain temporarily, then coagulating those nerves with a heat lesion should provide comparable, longer-lasting relief.

For the purposes of this systematic review, the procedure of interest is conventional thermal RFN, in which the target nerves are coagulated with electrodes that

produce a heat lesion at 80–90°C using a monopolar needle. This distinguishes the procedure from others, such as pulsed RFN, which operate by different mechanisms or techniques, and for which a different evidence base applies.

Systematic reviews of the literature on lumbar medial branch RFN have differed in their conclusions. Variously they reported that there is moderate evidence for efficacy [5,6]; level III evidence [7]; conflicting evidence [8–10]; evidence that supports RFN [11]; evidence of moderate quality that shows that RFN is more effective than placebo for short-term effects, but not in the long term [12]; level I evidence for short-term efficacy and level II evidence for long-term effectiveness [13]; and evidence that radiofrequency treatment is more effective than control treatments [14].

Practice guidelines are similarly varied in their recommendations. Those of the Philippines [15], the United Kingdom [16], the Netherlands [17], and Belgium [18] are permissive and entertain RFN after a positive diagnostic block. The guidelines of the American College of Environmental and Occupational Medicine provide no recommendation for or against RFN but do add that a diagnosis is required by medial branch blocks [19]. In contrast, Canadian [20] and US guidelines [21] and those of the Global Spine Initiative [22] found insufficient evidence to draw conclusions and, therefore, did not recommend RFN as a treatment. A review of guidelines identified German and Dutch guidelines that recommended against lumbar RFN [23].

To some extent, these differences in conclusions can be attributed to the types and number of studies on which they were based, and how stringently or liberally the outcome data were interpreted, but other potentially confounding factors apply. Authors of narrative reviews and other articles have variously pointed out that differences in the conduct and interpretation of diagnostic blocks, and differences in procedural technique, can have significant effects on the success rates of treatment and, therefore, on the validity and quality of evidence pertaining to lumbar RFN [7,24–32].

The purpose of the present study was, therefore, to review all of the literature on lumbar medial branch RFN while also stratifying the evidence according to patient selection and according to technique used. The null hypothesis tested was that differences in patient selection or procedural technique do not significantly affect the outcomes achieved.

Precepts

The paradigm of lumbar medial branch neurotomy allows for variables that potentially confound outcomes. These variables apply to the type of diagnostic block used, the definition of a positive response to blocks, the direction along which electrodes are applied to the target nerves, the gauge of the electrodes used, and how many lesions are applied to each target nerve.

Intra-articular Blocks

Intra-articular blocks have been used as a diagnostic procedure. However, the validity of intra-articular blocks has not been established; studies comparing intra-articular blocks and medial branch blocks have been insufficient. It is not known the extent to which positive intra-articular blocks are affected by false-positive responses, especially if intra-articular blocks are not controlled. If the false-positive rate is high, then substantial proportions of patients selected for treatment may not have the condition for which the treatment is designed and, therefore, would not respond to treatment, other than perhaps as a placebo response.

In addition, there is no direct connection between intra-articular blocks and medial branch neurotomy. Any connection is inferred: namely that if an intra-articular block relieves the patient's pain, then medial branch neurotomy should relieve that pain because the joint is innervated by medial branches. It has not been shown that the patients who respond to intra-articular blocks are the same patients who respond to medial branch blocks. Studies that have attempted to evaluate this, which are few in number, are limited by generous definitions of success, such as 50% and limited follow-up [33]. Equivalence of responses has not been demonstrated for greater degrees of relief of pain.

Medial Branch Blocks

Medial branch blocks have also been used as a diagnostic procedure. In theory, these have a more direct link to medial branch neurotomy. Medial branch blocks stop conduction along the target nerve using a local anesthetic agent. Theoretically, RF neurotomy should replicate that same relief by blocking conduction by coagulating the nerve with a heat lesion.

The face validity and target specificity of lumbar medial branch blocks have been established in normal volunteers [34,35] and in cadavers [36]. If the needle is placed accurately at the correct target point and if a small volume of local anesthetic (0.3–0.5 mL) is injected, it will capture the target nerve but will not anesthetize any other structure that is potentially an alternative source of pain. Before injecting local anesthetic, administering a small test dose of contrast medium [37] serves to avoid false-negative responses due to venous uptake of the subsequent injectate [35].

Construct validity pertains to the extent to which a positive response to a block is a true-positive response as opposed to a false-positive response. Construct validity cannot be assumed. Alterations in the number of blocks, the degree of relief obtained, and controlling for duration all factor into whether a reported positive response represents a true positive.

Single Blocks

Studies have shown that single medial branch blocks have a high false-positive rate (38–45%) [2,4,38–40]. If a sample of patients is selected for neurotomy on the basis of a single block, chances are that a large proportion of the patients will have had false-positive responses, and therefore these patients do not have the condition for which the subsequent treatment is suitable. Consequently, success rates will be diminished. A false-positive rate of 45% implies that nearly half of the patients selected would be compromised in this way, and success rates would be proportionately reduced.

Controlled Blocks

Performing a second block provides the opportunity to increase the likelihood of a true positive, which in turn serves to increase the success rate of treatment. This has been termed "dual comparative blocks" [41]. Beyond performing a second diagnostic block to increase specificity, a second block can also be used as a control in the form of a comparative block, which further increases specificity. Comparative blocks test for false-positive responses by comparing the durations of response when long-acting and short-acting agents are used for the two blocks. A positive response is one in which long-lasting relief occurs after a long-acting agent is used, and short-lasting relief occurs when a short-acting agent is used.

Comparative blocks were introduced on the basis of concept validity, that is, a theoretically good idea [42]. When tested against placebo in the conduct of cervical medial branch blocks, comparative blocks were found to have a sensitivity of 100% and a specificity of 65% [41], with a positive likelihood ratio of 2.86. If the duration of response is also considered, a concordant block further increases the specificity of the test to 88%, but at the expense of a decreased sensitivity of 54%, with a positive likelihood ratio of 4.5. However, these data are derived from a single study and have not been produced for lumbar medial branch blocks.

In principle, as random chance and placebo are eliminated from the test, specificity increases, which in turn may increase the success rate of the treatment both clinically and experimentally. In theory, false positives can be reduced further by randomizing which anesthetic is used [43]. The magnitude of how the specificity of the test accurately identifies patients further depends on the prevalence of the condition being diagnosed [44]. Suffice it to say, these issues are vital to understand when interpreting the literature. Given an overall low prevalence of lumbar zygapophysial joint pain [45] coupled with a test that has high rates of false positives, all studies that evaluate lumbar medial branch RFN have varying rates of patients who do not have lumbar zygapophysial joint pain and thus cannot respond to treatment beyond that of a placebo. For example, for a prevalence of 30%, even using concordant blocks with a positive likelihood ratio of 4.5, 33% of enrolled patients will not have lumbar zygapophysial joint pain. As this is a systematic review of lumbar medial branch RFN, further theoretical discussion of this is beyond the scope of this paper, though readers are directed to the referenced papers by Bogduk and Engel [43,44].

Degree of Relief

The magnitude of relief produced by a diagnostic block also influences the diagnostic accuracy of the test. An ideal response is complete relief of pain [43]. In practice, the threshold for degree of relief considered to be positive has varied in the literature and is frequently <100%.

Any response that is <100% relief of pain following a diagnostic block raises uncertainties. The patient may be uncertain about the effect of the block, "hedging their bets," having some sort of placebo response, or may have an additional source of pain. Whatever the reason, the validity of the response is questionable.

Although it is commonly held that 50% relief of pain means that the patient has some additional source of pain, this belief has not been verified. Such studies as have been conducted demonstrate that lumbar zygapophysial joint pain occurs in <5% of patients who also have disc pain or sacroiliac joint pain [46,47]. Other putative, concurrent sources of pain have not been investigated.

Electrode Direction

Laboratory studies have shown that RF electrodes produce little to no heat lesion distal to their tip; the heat lesion is produced circumferentially around the uninsulated shaft of the electrode [48]. Therefore, if electrodes are placed perpendicular to the target nerve, the risk arises of not capturing the nerve in a heat lesion, or capturing it only partially. Not capturing the nerve risks compromising the success rate of the procedure, because missing the nerve means not relieving the pain that it mediates. Capturing the nerve only partially risks providing only partial relief or only short-lasting relief, because the nerve recovers faster from only a partial lesion. Performing multiple lesions with a perpendicular approach may mitigate some but not all of this risk.

Alternatively, placing an electrode parallel to and directly along the nerve maximizes the extent that the nerve is exposed to the lesion [48]. These contentions were originally developed theoretically, on the basis of laboratory data, but circumstantial empirical evidence has since appeared. In a cadaver study, it was shown that electrodes positioned in a parallel trajectory to a medial branch consistently reached the target nerve and were parallel to it for a length of 9±2 mm [49]. When electrodes were introduced perpendicular to the target nerve, they missed the nerve in 30% of cases, and in the remaining cases captured the nerve for only 3±3 mm of the length of the nerve. In a clinical study, when the authors compared

their previous outcomes after using a perpendicular placement with subsequent outcomes when they adopted a parallel placement, they found a significantly greater success rate and significantly longer duration of benefit [50]. However, a prospective comparative study between these techniques has not been completed. This may explain why other reviews on lumbar medial branch RFN have not stratified based on this variable.

Electrode Gauge

If small-gauge electrodes are used, the risk arises of missing the nerve, which would be reflected by a diminished success rate. Even if placed in an apparently reasonable position, the heat lesion produced may coagulate the nerve incompletely, or only for a short length, which could be reflected by a reduced duration of effect.

Laboratory studies have shown that the radial diameter of the heat lesion produced by an electrode is proportional to the gauge of the electrode [48, 51]. For practical purposes, in order for the target nerve to be effectively within "reach" of the electrode, the electrode must be placed within two electrode widths of the target nerve. Consequently, as illustrated in a cadaver study [25], small-gauge electrodes (22 G, 20 G) must be placed virtually against the nerve. The tolerance is such that 1 mm of displacement may result in the heat lesion missing the nerve. Larger electrodes (18 G, 16 G) are more forgiving. So long as they are placed reasonably close to the nerve, the heat lesion they produce is likely to capture the nerve adequately.

Number of Lesions

Because small-gauge electrodes produce small lesions, and because the location of the target nerve may vary slightly, a single placement does not guarantee that the target nerve will be captured by the heat lesion. If single lesions are applied using small-gauge electrodes, the risk arises that the heat lesion may miss the target nerve or capture it only partially, even if the electrode is placed parallel to the course of the nerve. If small-gauge electrodes are used, performing multiple lesions in slightly different locations may mitigate this risk [52]. This is less of a problem with large-gauge electrodes, because a single heat lesion will cover a larger volume of the target zone. Even with large-gauge electrodes, at least two lesions will maximize the likelihood of fully capturing the target nerve [52].

Comparison of Techniques

The original technique for lumbar RFN was that developed by Shealy [53–56]. A procedure manual described and illustrated the technique to be used (Radionics) (Figure 1). Later anatomical studies showed that where electrodes were to be placed did not coincide with where

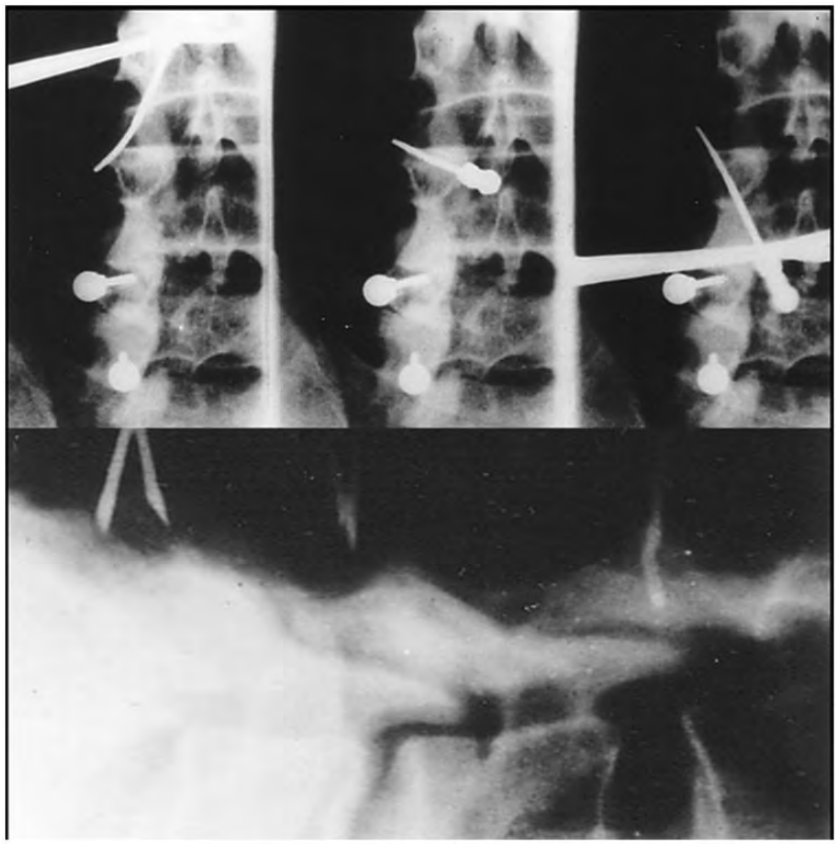

Figure 1. Radiographs illustrating the placement of electrodes using the technique of Shealy (Radionics).

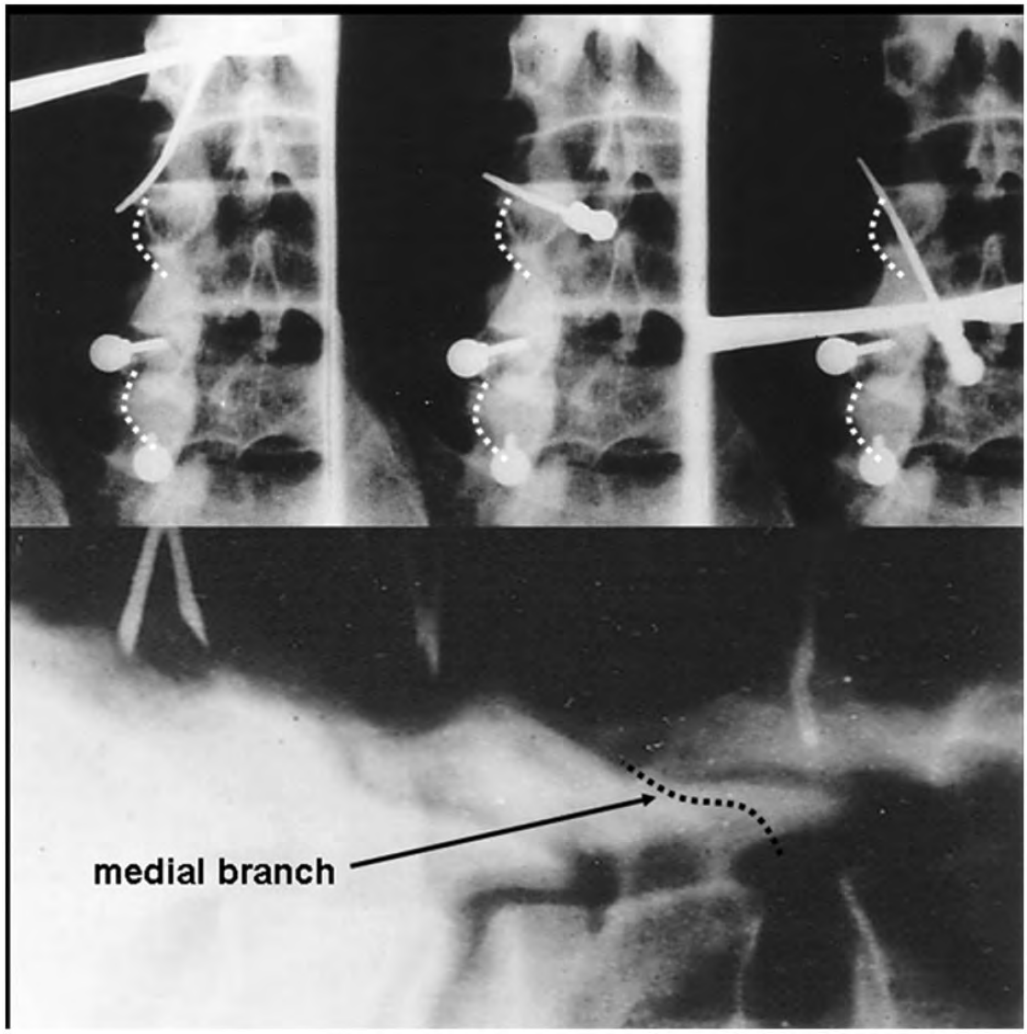

Figure 2. Copies of the radiographs of the Shealy technique (Figure 1), onto which the courses of the target medial branches have been drawn. At no placement of electrodes does the tip reach the nerve.

the target nerve was located [57,58]. The lumbar medial branches (and the L5 dorsal ramus) run across the neck of the superior articular process. In the Shealy technique, electrodes are placed variously lateral and caudal to the superior articular process, and at depths short of reaching the nerve (Figure 2). The nerve lies well out of range of any lesion generated by the electrodes.

Once the location of the medial branches was established, techniques were adapted to achieve anatomic accuracy [59,60]. The tips of the electrodes were correctly placed where the nerve was located (Figures 3 and 4). However, these adaptations were made before it was realized that electrodes produced minimal lesions distal to their tips. Therefore, electrodes were still placed perpendicular to the nerve.

A variety of techniques emanating from Europe have been described. Their common feature is that electrodes are inserted in a perpendicular fashion, in a manner similar to that in which needles are placed for diagnostic blocks. In none of these techniques was the placement of electrodes validated for accuracy in cadaver studies. The target points and placements were based on where the target nerve was presumed to run or lie.

The earliest described technique (Figure 3) correctly placed electrodes dorsal to the transverse process, and their tips were accurately located on the target nerve [60]. Moreover, large-gauge electrodes were used. Therefore, there is a reasonable chance that the small lesion made distal to the tip would encompass the nerve. Furthermore, since the technique called for multiple lesions to be produced along the course of the nerve, it is likely that a substantial length of the nerve would be coagulated. However, no adequate studies reported the effectiveness of this technique, which seems to have been supplanted by different techniques using smaller electrodes with different placements.

The first of these latter techniques [61] called for electrodes to be placed above and beyond the superior border of the transverse process (or over the superior border of the ala of the sacrum, for the L5 nerve) (Figure 5). Ostensibly,

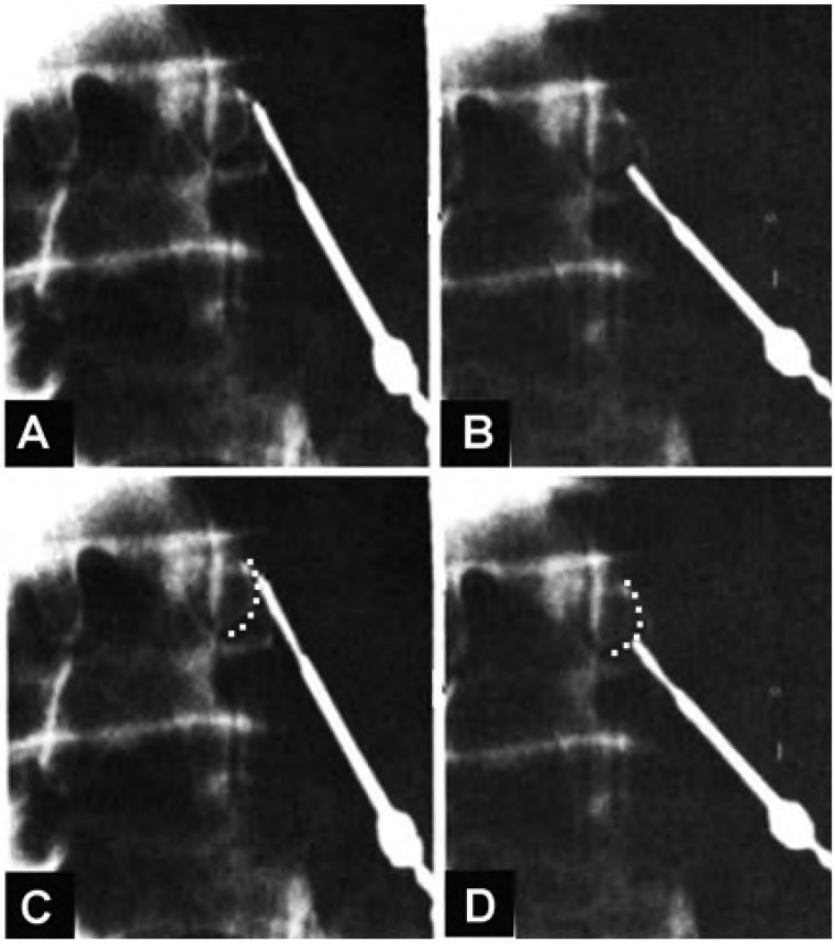

Figure 3. Radiographs of electrodes placed for lumbar radiofrequency neurotomy, published in 1979 [60]. A and B) Copies of the original radiographs. The technique recommends placing a lesion proximally and distally along the course of the nerve. In (C and D), the course of the medial branch has been depicted as a dotted line. It is evident that the tip of the electrode lies on the target nerve in each position.

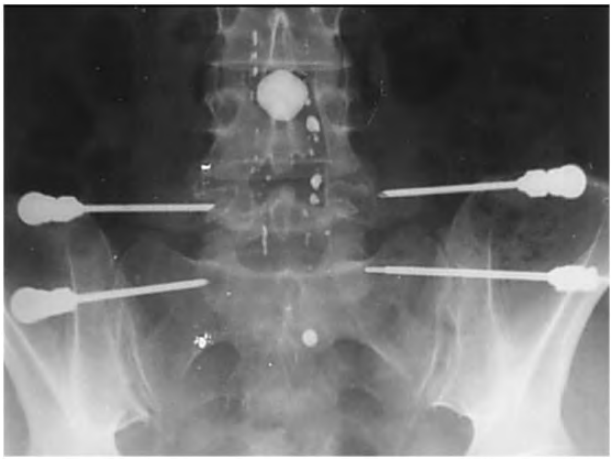

Figure 4. A radiograph of placement of guide cannulae and an electrode for lumbar medial branch radiofrequency neurotomy, published in 1980 [59].

but never explicitly stated, the target nerve must be the dorsal ramus, for at typical segmental levels, the medial branch lies dorsal to the transverse process, against the neck of the superior articular pillar [25]; only the dorsal ramus lies ventral to the plane of the transverse process.

Inspection of the radiographs illustrating this technique reveals inconsistencies in matching the location of the electrodes and the location of the target nerve. As shown in Figure 5, the antero-posterior view shows the electrode at L3 close to where the L3 dorsal ramus is expected to lie, but the lateral view suggests that it may be too far dorsal to reach the nerve. The electrode at L4 is displaced superolateral to the course of the nerve and may or may not be deep enough. At L5, the electrode lies deep enough to reach the L5 dorsal ramus according to the lateral view, but the antero-posterior view shows that the electrode lies more than two electrode widths lateral to nerve. Given the small-gauge electrodes used and, therefore, the small lesions that they produce, these various placements are too inaccurate to guarantee always capturing the target nerve.

In another perpendicular technique, it is not clear if the target nerve at typical lumbar levels is the dorsal ramus or the medial branch [62]. The electrodes are inserted obliquely toward the nerve, but nonetheless perpendicular to the course of the nerve. When electrode placements are

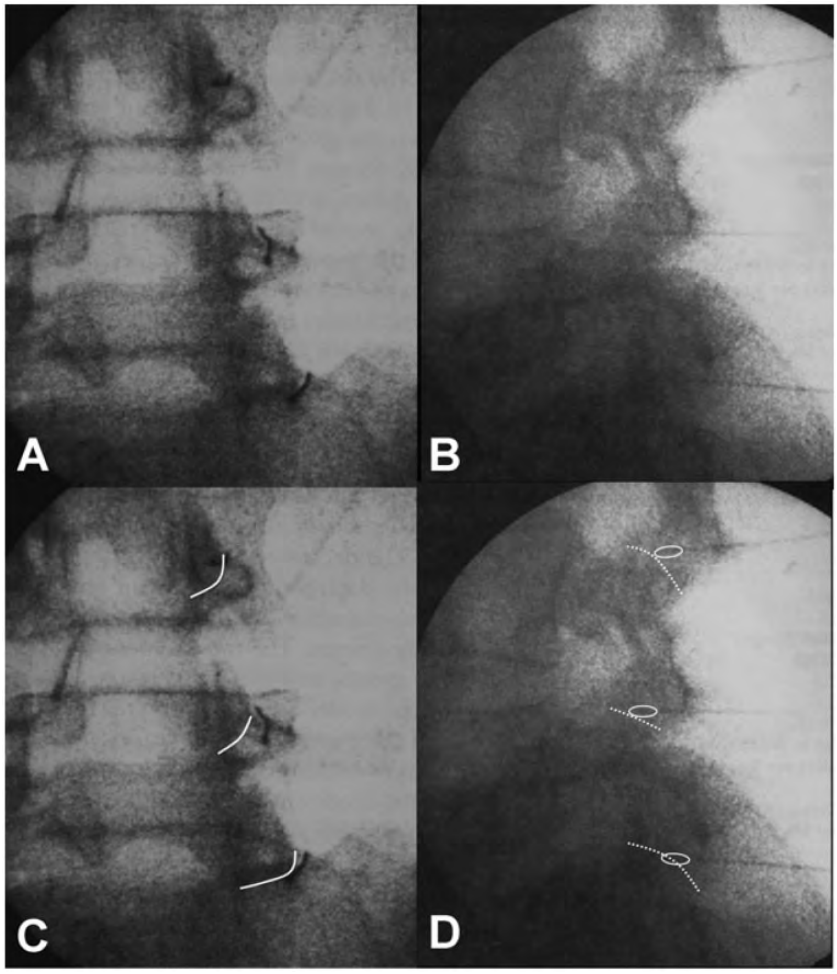

Figure 5. Radiographs illustrating an early technique for lumbar radiofrequency neurotomy using perpendicular placement of electrodes [61]. A and B) Copies of the original illustrations as published, showing antero-posterior and lateral views of electrodes placed on the L3, L4, and L5 target nerves. In (C), the courses of the L3 and L4 medial branches and the L5 dorsal ramus have been added. In (D), the courses of the nerves have been drawn as dotted lines, and ellipses have been drawn around the tips of the electrodes to indicate the expected size of the thermal lesions produced by the electrodes.

compared with the location of the nerves, two types of irregularities arise (Figure 6). In some instances, the tip of the electrode is not in the vicinity of the target nerve, whether it is the medial branch or the dorsal ramus. In other instances, the tip of the electrode seems to be reasonably in contact with the nerve, but because the electrode has been inserted perpendicular to the course of the nerve, most of the lesion that the electrode produces will be peripheral to the nerve, that is, back along the shaft of the electrode, away from the nerve (Figure 6).

In a recent version of a perpendicular technique, the target nerve was expressly the medial branch as it crosses the superior border of the transverse process [63]. The guidelines for the procedure call for electrodes to be placed just over the superior border of the transverse process (or the ala of the sacrum for L5) [63]. Illustrations of the placement, however, show that the electrodes are placed substantially lateral to the location of the nerves, such that the lesions produced by the electrodes would likely miss the nerve or barely reach it (Figure 7).

The common feature of all three latter techniques is that placement of electrodes is illustrated but without regard to if electrodes actually contact the nerve and whether the lesions made actually capture the nerve. Variously, the lesions made would lie proximal to the nerve or lateral to it and would fail to encompass the nerve or would barely do so. If small-gauge electrodes are to be used, the electrode must lie in contact with the nerve in order for the lesion produced to fully encompass the nerve [25]. Consequently, electrodes must be placed exactly on the nerve, not simply nearby.

The technique for lumbar medial branch RFN, as promoted by the International Spine Intervention Society [64], was developed in cadaver studies, in which electrodes were placed on dissected medial branches (Figure 8) and then radiographed [25]. These radiographs provided images of what electrodes would look like when correctly placed, parallel with and in contact with the target nerve (Figure 9). When correctly placed in patients, the electrodes should assume that same appearance (Figure 10). At

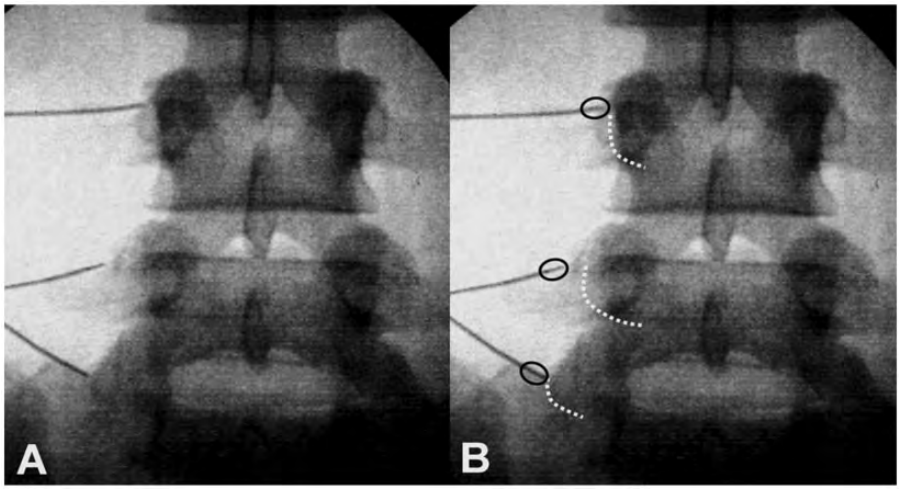

Figure 6. Radiographs of a second perpendicular technique [62]. A) A copy of the original illustration. In (B), the courses of the medial branches have been added as white dotted lines; the sizes of the thermal lesions made by the electrodes are shown as black ellipses. The electrode for the L4 medial branch fails to reach the target nerve; its tip lies substantially lateral to the nerve. The tips of the electrodes for the L3 and L5 nerves are likely to have reached the nerve, but the lesions that these electrodes make barely reach the nerve, if at all.

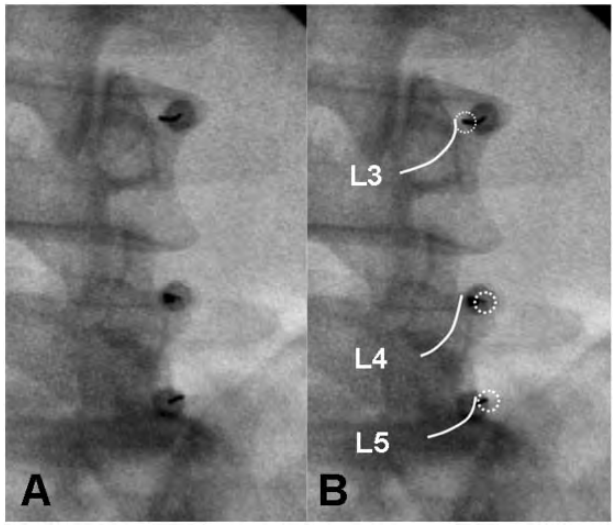

Figure 7. Radiographs illustrating electrode placement from the procedural guidelines of a recent study of lumbar radiofrequency neurotomy using perpendicular placement of electrodes [63]. A) A copy of the original published radiograph. In (B), the courses of L3 and L4 medial branches and the L5 dorsal ramus have been drawn as white lines, and dotted circles show the size of the lesions made by the electrodes. It is evident that the electrodes lie lateral to the location of each nerve, and the lesions made by the electrodes would not reach the nerves.

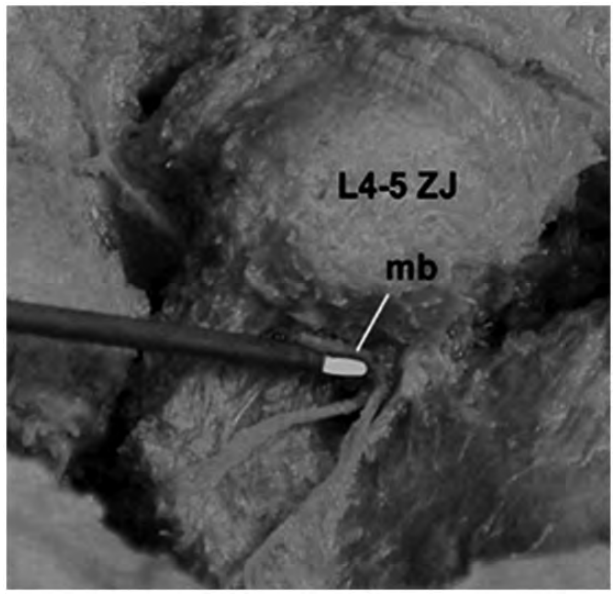

Figure 8. A close-up view of a dissection of the branches of a right L4 dorsal ramus, with the medial branch labeled (mb), crossing the neck of the L4-5 zygapophysial joint (ZJ). A 16-gauge radiofrequency electrode has been placed parallel to and in contact with the medial branch. The 5-mm active tip of the electrode has been enhanced in white.

typical lumbar levels (L1–L4), the target nerve is the medial branch. At L5, the target is the dorsal ramus itself, because the L5 medial branch does not arise until the caudal margin of the L5–S1 zygapophysial joint [65].

The principal difference in this technique from preceding techniques is that the electrode is placed parallel, not perpendicular, to the nerve. Furthermore, an additional radiographic view is used, called the declined view. The x-ray beam is tilted caudally in order to view the transverse process from behind and below. This view shows the junction of the superior articular process and transverse process in cross-section. The electrode is introduced so that it lies within one electrode width from the neck of the superior articular process (Figure 10A), which is where the target nerve runs.

Based on these precepts, for the purposes of this review, if a procedural technique did not employ parallel placement of large-gauge electrodes, it was considered

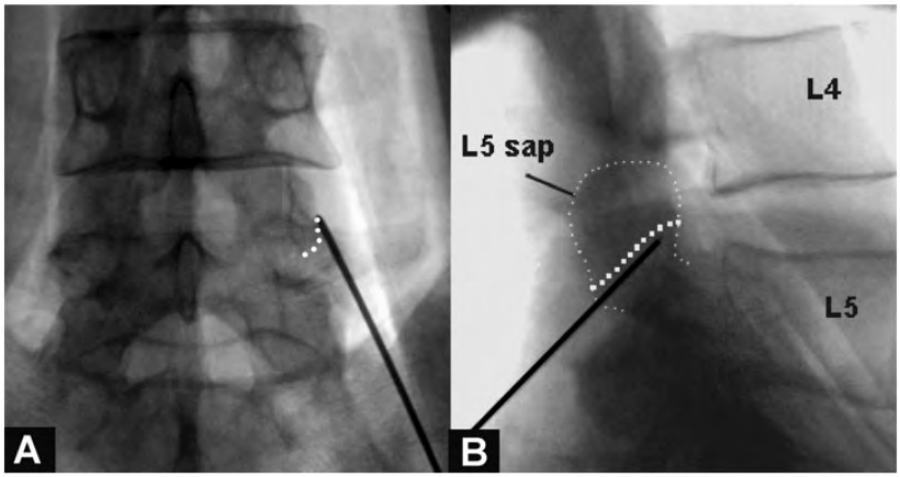

Figure 9. Radiographs of a cadaver in which an electrode has been placed parallel to and in contact with an L4 medial branch, as illustrated in Figure 1. The white dotted line depicts the course of the medial branch. A) Anteroposterior view. B) Lateral view, showing the nerve and electrode crossing the neck of the L5 superior articular process (sap).

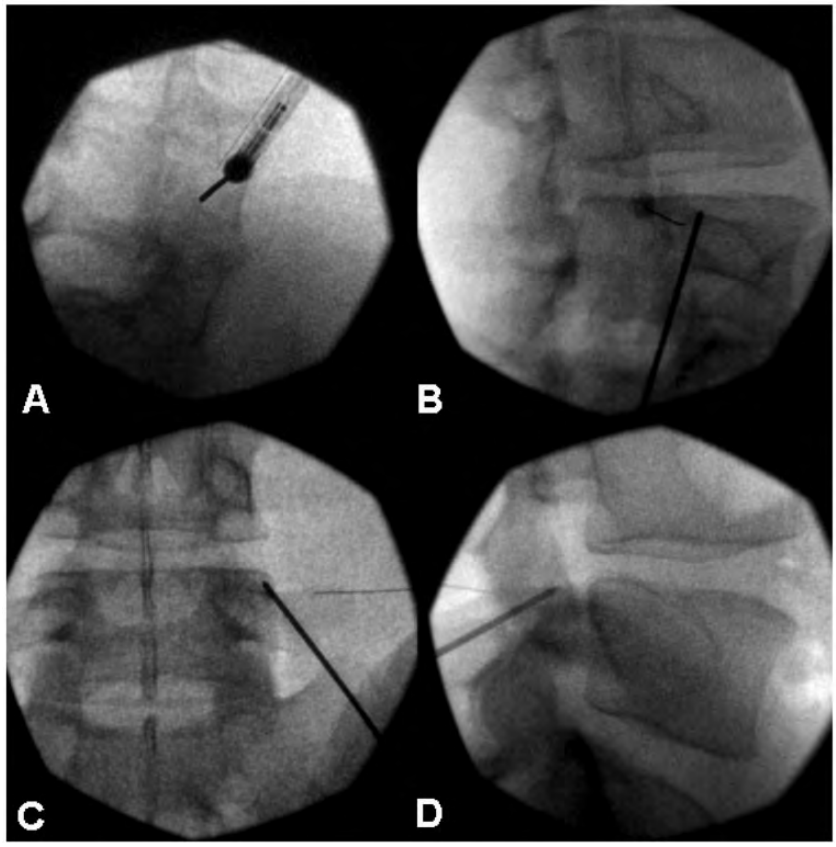

Figure 10. Radiographs of an electrode in place against an L4 medial branch, taken during an actual procedure. A) Declined view, showing an electrode against the neck of the superior articular process of L5. B) Oblique view, showing the electrode crossing the junction of the superior articular process and transverse process. C) Antero-posterior view, showing the electrode placed obliquely against the superior articular process. D) Lateral view, showing how the electrode crosses the neck of the superior articular process.

"suboptimal," as it could readily be surmised that it did not maximize the likelihood of capturing the nerve or the extent of the nerve lesioned.

Methods

The literature was searched for any studies that provided original data on the effectiveness of lumbar medial

branch RFN. Eligible for inclusion were observational studies and randomized controlled trials.

A first literature search was conducted in May 2017. The databases Cochrane Central Register of Controlled Trials, Ovid MEDLINE, Embase, and PsycINFO were interrogated using the same search terms and strategy implemented by the 2015 Cochrane Review [12]. These terms included, but were not limited to, backache, back near pain, facet near pain, radiofrequency, thermocoagulation, electrocoagulation, neurotom*, neuroly*, and denervation. As the study progressed, a second search was conducted in October 2018 using the same databases and search terms in order to check for any new articles that had been published since the first search.

After each search, each member of the investigating team screened the titles and abstracts of the articles listed by the search in order to identify potentially eligible articles and articles that patently were not eligible. The latter were editorials, commentaries, essays, and reviews that relied on citations but did not provide original data. They also included articles that used RFN to treat conditions other than back pain mediated by lumbar medial branches or ostensibly stemming from the zygapophysial joints. Examples of the latter included the treatment of disc pain, sacroiliac pain, and tumors.

Copies of full versions of potentially eligible articles were obtained. These were divided alphabetically into three batches, which were assigned to three teams of two investigators. These investigators independently assessed their assigned articles, guided by the following five questions.

- Does the article provide evidence on the effectiveness or efficacy of lumbar RFN?
- Is the procedural technique unambiguously described?
- Are the selection criteria for treatment clearly described?
- Does the article provide categorical data from which success rates can be calculated?
- Are the methods used sufficiently rigorous for the conclusion to be valid and convincing?

Studies were then assessed for the degree to which their data were credible and compelling [66]. Rated highly were studies that were prospective and that described their source population, their selection criteria, the demographic and clinical features of the sample, segmental levels diagnosed and treated, the technique used for RFN, baseline values for pain and other outcome variables, the methods used for collecting outcome data, the use of an independent assessor, and in which relief of pain was corroborated by significant improvements in other outcome measures.

Effectiveness was quantified in terms of success rates via categorical data on the numbers (and proportions) of patients treated who obtained clearly defined outcomes. For relief of pain, categories of outcomes that were considered informative were minimal clinically important changes, 50% relief of pain, greater degrees of relief, and complete relief of pain. For other outcomes, such as disability or function, and in the use of other health care, similar categories were accepted. If studies did not expressly state such outcomes, they were nevertheless accepted if they reported data from which such outcomes could be calculated. When required, these calculations were performed by the investigator responsible for reading the paper in the first instance; later, such calculations were checked by all investigators.

Unique to this comprehensive systematic review is that the studies were also stratified according to the precepts described above. The cardinal strata were selection by one or two diagnostic blocks, 50% relief of pain or more after blocks, and perpendicular or parallel placement of electrodes. Note was taken of the gauge of electrode used and the number of lesions made, in case stratification needed to be extended according to these variables.

Once completed, the evaluations produced by each investigator were shared and discussed at meetings, until all investigators agreed on the final version.

The body of evidence in each category of the stratification was then evaluated according the principles of Grading of Recommendations, Assessment, Development and Evaluations (GRADE) [67]. These principles address quality of evidence, risk of bias, and estimate of effect. Evidence is considered of high quality if randomized controlled trials (RCTs) are available, but low if the evidence is exclusively derived from observational studies. That quality can then be upgraded or downgraded according to the risk of bias and consistency of estimates of effect.

Results

Excluded Studies

Although their titles appeared to be relevant to the present review, several studies were rejected from inclusion in the analysis for a variety of reasons. Articles published only in abstract form were not included in the final analysis, for lack of sufficient information about methods used, lack of detail on techniques for diagnosis or treatment, and lack of detailed corroborating quantitative data on outcomes. Some proved to be simply essays or abstracts of lectures that contained no original data [60,68–73]. Others did not use any form of diagnostic blocks to select patients [74,75], only described how to perform the treatment [76,77], or had too few patients in their sample to provide a meaningful estimate of effect [78,79].

Included Studies Stratified

Intra-articular Blocks

Five studies used single intra-articular blocks to select patients for treatment by RFN [33,62,80–82]. Four of these studies used a suboptimal technique [62,80–82]; the other used a parallel technique [33]. In three of the

studies, 50% relief from a single block was the selection criterion [33,62,80]. In the other studies, the criteria were "clear relief" [82] and "significant relief" [81], but these criteria were not further defined.

The four studies that used suboptimal procedural techniques were all RCTs. In three of them, the control was sham RFN [62,81,82]; in the other study, the control was an intra-articular injection of steroids [80].

The first study [82] used the Shealy technique (see *Comparison of Techniques*, above) (Figures 1 and 2). The study did not provide categorical data, so the effectiveness of treatment could not be calculated. On the basis of group data (mean pain scores), the study claimed that active treatment was more effective than sham treatment at one month and at six months. Scores on the McGill Pain Questionnaire corroborated this difference at one month but not at six months.

The second study [81] used a modification of the suboptimal Shealy technique but without providing further details. This study did not report any data on success rates for achieving either 50% relief of pain or complete relief. It provided only group data, which showed that after treatment mean scores for pain of the actively treated group were not significantly different from those of the sham-treated group. Indeed, at 12 weeks, in the actively treated group, the mean change in pain from baseline was zero. In a subsequent letter to the editor, the authors acknowledged that their selection criterion and their procedural technique were both suboptimal and that their study was not a valid test of how lumbar RFN should be practiced [83].

The technique used in the third study [80] was poorly described. Purportedly, the procedure was performed according to the standards of the International Spine Intervention Society and, therefore, involved parallel placement of electrodes, but radiographs of the placement were not provided. The study reported that RFN was not significantly more effective than intra-articular injection of steroids, but no success rates were provided.

The fourth study [62] used a perpendicular placement of 22-G electrodes. The study reported that the success rates for achieving 50% relief of pain at three months were 33% (95% confidence interval [CI] = 18–48%) in the actively treated group and 34% (95% CI = 19–49%) in the control group; these success rates were not significantly different statistically. No data on complete relief of pain were reported. Following the publication of this study, it was shown that the procedural technique used was inaccurate [84]: Electrodes were placed in locations that did not coincide with the locations of the target nerves (Figure 6). In reply, the authors explained that they had studied how RFN is practiced in the Netherlands [85]. Consequently, their results apply only to that practice and, per the authors, do not have external validity to other versions of lumbar medial branch RFN.

Collectively, these latter three studies provide strong evidence that selecting patients with intra-articular blocks and then using suboptimal procedural techniques is no more effective than sham treatment. Furthermore, the studies provide little evidence on just how effective RFN is under these conditions. Only one of the three studies provided data on success rates. Those data indicate, at best, that only 33% (95% CI = 18–48%) of patients achieve the modest outcome of 50% relief of pain at three months.

From these three studies alone, it is not evident if these modest outcomes are due to the use of intra-articular blocks to select patients, the use of only a single diagnostic block, the use of 50% relief from a block as the selection criterion, or the specious procedural technique used. The fifth study [33], however, sheds light on this issue.

In that study, as in the other studies, patients were selected for treatment on the basis of 50% relief from a single intra-articular block, but RFN was performed using an optimal procedural technique, that is, parallel placement of electrodes. This study, therefore, serves as a control for procedural technique. At three months after treatment, 56% (95% CI = 41–71%) had a successful outcome, but success was defined by a reduction of numeric pain score by at least 2/10, which is the conventional minimal clinically important change for back pain. No data were presented for more demanding criteria such as 50% relief of pain or complete relief. At six months, the success rate had dropped to 24% (95% CI = 12–36%) and was statistically indistinguishable from the success rate of treating patients who had no response to sham medial branch blocks (17%, 95% CI = 6–28%).

Collectively, these five studies show that, regardless of the procedural technique used, the success rates of RFN are low, even for generous definitions of success, if patients are selected for treatment using a single intra-articular block. Furthermore, these success rates are no better than those achieved in patients selected by sham blocks or treated with sham RFN.

In terms of GRADE, the body of literature on using intra-articular blocks to select patients must be considered of high quality, because it consists largely of randomized controlled trials. However, the evidence shows that the effectiveness of subsequent treatment is low, regardless of whether perpendicular or parallel placement of electrodes is used. The risk of bias in the RCTs is low, and the estimates of effect are quite consistent. Therefore, there are no grounds for downgrading the quality of this evidence.

Single Medial Branch Blocks, Perpendicular Electrodes

Three publications were considered to provide direct and valid data on the effectiveness of RFN using single medial branch blocks as the selection criteria and perpendicular electrode placement as the technique [61,63,86]. Five articles were not included. One article [87] was an essay on prognostic factors. It mentioned achieving good outcomes from RFN, but it provided no information on

demographic features, clinical features, pain scores, other outcome measures, how patients were selected, how patients were treated, or how patients were followed and assessed. In another study, [88] the procedural technique was not described, and no data on success rates were provided. The third study [89] illustrated the technique used, but electrodes were placed in unacceptable locations that are not representative of any other standardized technique for RFN. Therefore, the data are not applicable to any other technique described in the literature. The fourth study [90] claimed improvement from treatment but did not define improvement. The fifth study [91] was neither designed nor conducted as an outcome study. It was a retrospective study of patient records to determine the influence of clinical signs on outcomes.

Three studies provided sufficient data to draw conclusions about the effectiveness of perpendicular placement of the RF electrode. Each was an RCT. In two trials [61,63], the selection criterion was at least 50% relief from a single medial branch block. The third study [86] applied a more generous selection criterion of a decrease in numeric pain score by 2/10.

The study of van Kleef et al. [61] reported that active RFN was more effective than sham RFN, which defined success as a reduction of pain by 2/10. Independent analysis of the data provided in the paper shows that for success defined as at least 50% relief of pain, 46% (95% CI = 21–71%) of patients achieved this outcome at two months after active RFN and 25% (95% CI = 5–45%) achieved it after sham treatment; the difference was not significantly different statistically, ostensibly because of the small sample sizes (15 and 16).

The study of van Tilburg et al. [86] reported that 22% (95% CI = 7–37%) of patients achieved 50% relief at one month after active treatment, but so did 32% (95% CI = 15–49%) after sham RFN.

The study of Juch et al. [63] defined success as a 30% reduction in pain. Of the patients treated with RFN plus exercises, some 50% achieved a successful outcome at three, six, nine, and 12 months, but so did similar proportions of patients treated with exercises alone. Although a perpendicular technique was described, the images provided demonstrate that the electrodes also lay lateral to the location of each nerve, and the lesions made by the electrodes did not reach the nerves (Figure 7).

When pooled, the data from two of these studies [61,86] indicate that when utilizing single medial branch diagnostic block achieving 50% relief for inclusion coupled with a small-gauge electrode placed via the perpendicular approach, the chances of patients obtaining 50% relief at one month are 26% (95% CI = 12–40%). Data from the other study [63] could not be included because that study did not report how many patients achieved 50% relief or greater.

Collectively, these studies indicate that if patients are selected on the basis of $\leq$50% relief after a single diagnostic block, and if only one lesion is delivered from an electrode placed perpendicular to the target nerve, the success rates for achieving 50% relief of pain are low. Furthermore, these success rates are not significantly different from those achieved by sham RFN or by exercises.

An observational study [92] ostensibly used a perpendicular technique, but the authors indicated that they delivered RF lesions at three or four locations along the course of the target nerve, a modified technique more akin to a parallel approach in terms of the lesion area generated. This study is included below, under *Single Block, Modified Technique*.

Collectively, the evidence for selecting patients with a single medial branch block and treating them with electrodes placed perpendicularly qualifies as high quality, because it stems from RCTs. Moreover, the consistency between studies suggests that the estimate of effect is reasonably accurate. So, the quality of evidence does not warrant being downgraded. However, that evidence indicates that the effectiveness of lumbar RFN under these conditions is poor.

Two Blocks, Perpendicular Electrodes

Four studies used two diagnostic blocks and what appeared to be perpendicular placement of electrodes [93–96]. Three of the studies used two medial branch blocks to select patients [94–96]; the other used a first intra-articular block and a second medial branch block [93].

One study [96] addressed the number of patients who benefitted from repeat treatment once their response to original treatment waned but did not report the original success rates. In the second study [95], no data on success rates were reported, and 48% of patients treated were lost to follow-up. The third study [94] reported that 60% (95% CI = 46–74%) of patients achieved at least 50% relief of pain at six months. However, this was discordant with only 38% (95% CI = 24–52%) rating their response as "very good." This estimate of effect was determined to have potential for bias because outcomes were not assessed by an independent observer, and the study was downgraded. The fourth study reported the results of seven audits conducted over a three-year period [93], but success was defined as only an estimate by the patient of at least 50% relief, with no corroborating data on numeric pain scores or other outcomes. This study was also downgraded due to the unvalidated outcome measure.

For selecting patients with two blocks and treating them with electrodes placed perpendicularly, the evidence rates as low quality. It derives exclusively from observational studies of poor quality methodologically, to the extent that no valid conclusions can be drawn from this literature.

Single Medial Branch Block, Parallel Electrodes

One study [97] selected patients who had 75% relief following a single medial branch block. It claimed to have

used a parallel approach, but independent review of the figures shows a perpendicular approach, as agreed upon by this author panel. Although it claimed favorable long-term outcomes after RFN, outcomes were based on self-reported estimates of effects, with no validated objective quantitative data. For these reasons, it could not be included in the analysis.

The study by Tekin [98] is an RCT that reported that active RFN was significantly more effective statistically at reducing pain scores than was sham RFN. Of the patients treated with active RFN, 65% (95% CI = 45–85%) rated their response as excellent, compared with only 20% (95% CI = 2–38%) of those who had sham treatment. However, because the study did not provide categorical data on success rates using a validated objective quantitative measure, it was excluded from the final analysis.

Several studies used parallel placement of electrodes to treat patients who reported at least 50% reduction of pain after a single medial branch block [33,99–103]. Of these studies, one defined success as achieving a 2/10 improvement in numeric pain score but provided insufficient data to determine how many achieved ≥50% relief of pain [33]. Because these data were not compatible with the outcomes obtained from the other studies included in our final analysis, it was excluded.

Two studies reported outcomes only at three months [100,101]. For achieving 50% relief of pain, their success rates were 39% (95% CI = 17–60%) [101] and 58% (95% CI = 43–71%) [100].

For achieving 50% relief of pain at six months after RFN, the other studies reported success rates of 66% (95% CI = 55–71%) [103], 54% (95% CI = 47–61%) [99], and 47% (95% CI = 31–63%) [102]. In each of these studies, relief of pain was variously corroborated by improvements in function, patient satisfaction, and reduction in use of analgesics.

When these latter data are pooled, they indicate that if patients are selected on the basis of 50% relief from a single medial branch and are treated with electrodes placed parallel to the target nerve, their chances of getting 50% relief of pain at six months are 57% (95% CI = 52–62%).

In terms of GRADE, the evidence for this section notionally qualifies as high quality. Although there is only one RCT, the results of all the observational studies are consistent with the results of this trial. That consistency provides grounds for not downgrading the quality of evidence because further studies might produce contradictory results.

Single Block, Modified Technique

Included here is the study of Yilmaz et al. [92]. Although the investigators approached the target nerve using a perpendicular approach, they delivered three or four lesions along the length of the nerve. In this regard, the technique is dissonant from any other study reporting a perpendicular technique and is more consistent with earlier techniques (Figure 3) [60]. Multiple lesions along the course of the nerve render the technique more equivalent, in terms of lesion size and area, to a parallel placement of electrodes. The diagnostic criterion in this study was 80% relief from a diagnostic block, greater than the 50% criteria used by Cohen, Cohen, Tome, and Derby in the above section. In this study, 86% (95% CI = 76–96%) achieved 60% relief at six months and 12 months. This success rate is dissonant with the success rates of all other studies of lumbar medial branch RFN, regardless of technique used, and therefore may be an overstatement. Indeed, the study itself reported that only 64% (95% CI = 51–77%) required no other treatment for their pain after RFN. Therefore, this latter figure might be a more accurate estimate of the success rate.

Two Blocks, Parallel Electrodes

Several studies used parallel placement of electrodes to treat patients selected on the basis of positive responses to two diagnostic blocks. Not all could be included in the present analysis, for various reasons.

Two studies reported results favorable to lumbar medial branch RFN but provided only group data for relief of pain, from which success rates could not be calculated, and thus were excluded from the final analysis [104,105]. Another study addressed the success rates of repeat RFN but did not report the success rates of the initial cohort; only the initial success rates of those who came to repeat treatment were reported [106].

Three studies were not included because they treated atypical samples of patients who were not representative of the general population in which lumbar RFN is typically applied. One study treated patients with persistent pain after spinal surgery [107]. The other exclusively treated a small sample of 12 baseball players [79]. Likewise, another study was not included because it, too, treated only patients with spondylolisthesis [108]. These studies were excluded due to a lack of external validity; it would not be legitimate to compare their success rates with those obtained in more general samples.

Despite reporting good outcomes from lumbar RFN, a sixth study was rejected because it was not a formal outcome study. Rather, it was a retrospective search of records, whose objective was to determine if and how often back pain could be attributed to a zygapophysial joint or joints in patients with a variety of pathology documented on magnetic resonance imaging [109].

A final study was a placebo-controlled RCT [110]. On the basis of group data, it showed that improvements in pain and function after active RFN were significantly greater statistically than after sham RFN, but this study did not report any data from which success rates could be calculated, and thus was excluded from the final analysis.

The studies that were included in the analysis all used reasonably similar procedural techniques in which electrodes were placed parallel to the target nerve or nerves. However, they differed in their criteria for a positive response to diagnostic blocks, and could be stratified accordingly.

Three studies required 50% relief from diagnostic blocks. One of these studies used either an intra-articular block or a medial branch block supplemented by a medial branch block [111]; the other two studies both used two medial branch blocks [101,102]. For achieving 50% relief of pain after RFN, these studies reported success rates of 64% [101] and 57% [111] at three months and 77% [102] and 39% [111] at six months, the latter dwindling to 20% by 12 months [111]. When pooled, these data indicate that patients have a 63% (95% CI = 50–76%) chance of achieving 50% relief of pain at three months. For achieving 50% relief at six months, the chances are 49% (95% CI = 36–62%).

Other studies required higher grades of relief from two medial branch blocks. One study required 70% relief [112], three required 80% relief [113–115], and one required complete relief of pain [116]. Furthermore, for a successful outcome, these studies targeted higher grades of relief than only 50% relief of pain.

Of the studies that used 70–80% relief of pain after diagnostic blocks, one reported achieving >50% relief in 57% of patients at six months after RFN, of whom 22% had at least 80% relief [112]; another reported 80% relief in 60% of patients at 12 months [113], and the third study reported complete relief in 35% of patients at six months, with a further 14% achieving >75% relief, and 16% with 50% relief [114]. In the fourth study, high grades of relief were not achieved [115], and only 28% of patients achieved 50% relief.

The study that required complete relief after diagnostic blocks also set high standards for the definition of success. Patients had to have complete relief of pain, accompanied by restoration of activities of daily living, and no need for other health care for back pain [116]. This outcome was achieved and lasted at least six months in 56% of patients and 12 months in 36% of patients.

When the data from the studies that required high grades of relief from diagnostic blocks are pooled, the following figures arise.

If the criterion for selection was >70% relief from diagnostic blocks, patients had a 58% chance (95% CI = 54–62%) of obtaining 50% relief for six months, a 36% chance (95% CI = 32–40%) of obtaining 80% relief for six months, and a 23% chance (95% CI = 20–26%) of obtaining complete relief for six months. In these figures, the 95% confidence intervals are tight, because several of the sample sizes were large.

If the criterion for selection was raised to complete relief of pain from diagnostic blocks, patients had a 56% chance (95% CI = 47–65%) of complete relief of pain at six months and, by inference, had the same or greater chance of 80% relief or 50% relief.

In terms of GRADE, this body of evidence can be considered high quality. There are several observational studies and one RCT with consistent results. Because of the large sample sizes studied, that consistency applies not only to success rates for achieving 50% relief of pain but also to achieving 80% relief and complete relief.

Two Blocks, Modified Technique

Another study selected patients based on complete relief and treated with multiple lesions along the course of the nerve, which notionally makes the treatment similar to a parallel placement [117]. No baseline data were reported. At three months after treatment, the success rate of active treatment was not significantly greater than that of sham treatment, but at six months, 12 months, 24 months, and 36 months, the success rate was significantly better than that of sham treatment. There was no description of how follow-up was obtained, nor description as to whether other treatments were controlled for. This study was downgraded and thus excluded from analysis over concerns with the internal validity of the data, most notably the lack of baseline data and unexplained differences that did not occur until six months post-treatment.

Electrode Gauge

There is insufficient evidence to allow valid conclusions to be drawn concerning the influence on effectiveness of the gauge of the electrode used. Basic science studies have shown theoretically that 16-G electrodes produce larger lesions than do 21-G electrodes and are, therefore, more likely to encompass the target nerve adequately [25]. Small-gauge electrodes must be placed virtually exactly on the nerve in order to capture it, unless multiple lesions are made to coagulate the entire target zone in which the nerve may possibly lie [25].

Circumstantial evidence is consonant with this contention. Two benchmark studies that reported good and lasting success rates both used 16-G electrodes [113,116], but these studies also used stringent selection criteria and accurate procedural techniques. A third study, which also reported good success rates [112], used either a 16-G electrode or a 22-G electrode placed in three positions.

In contrast, all studies that used small-gauge electrodes placed in a single position had modest or poor outcomes, but these studies also used less stringent selection criteria or less than optimal procedural techniques.

However, no studies that used comparable selection criteria and comparable techniques have differed in the gauge of electrode used. Consequently, there is no evidence that directly shows that larger-gauge electrodes,

rather stringent selection and accurate procedural technique, are responsible for optimal outcomes.

Repeat Treatment

Lumbar medial branch RFN is not designed to be a permanent cure for back pain. It does not address the causative pathology. Instead, it coagulates the nerves that mediate the pain, causing extensive damage to them [118], thereby blocking conduction along them. However, the dorsal root ganglion, in which the cell bodies of the targeted nerves reside, is not affected. Therefore, the nerves can regenerate in time and resume nociceptive transmission. The regeneration time is variable and presumed to be, at least in part, related to the length and completeness of the nerve lesion.

When pain recurs, however, the treatment can be repeated in order to reinstate relief. Several studies attest to successful renewal of relief [106,116,119,120]. In some patients, relief is not reinstated by repeat treatment, which suggests an error in the original diagnosis or in the diagnosis of the renewed pain. However, in most patients, relief can be reinstated.

Those studies that have published data indicate that if the diagnostic criterion and the definition of success are both 50% relief of pain, the success rates of repeat RFN are of the order of 50% [106] or >85% [119]. When the diagnostic criterion and the definition of success have both been complete relief of pain, all patients responded to repeat RFN [116]. When repeat treatments have been applied, the documented, cumulative durations of complete relief of pain have exceeded 20 and 30 months, with the longest being >100 months, with a median duration of 13 months per treatment [116].

Summary Statistics

Table 1 summarizes the quantitative data available in the literature on the effectiveness of lumbar medial branch RFN. It also shows certain trends, some of which are statistically significant.

In the first instance, it is quite clear from the published data that lumbar medial branch RFN has a low success rate (26%) when performed using perpendicular placement of electrodes in patients who get 50% relief from a single diagnostic block. Furthermore, for achieving 50% relief after treatment, this success rate is significantly lower statistically than the success rates of parallel placement of electrodes, irrespective of the selection criterion applied. Moreover, for perpendicular placements, success rates have been published only for outcomes at one month or two months. For parallel placements, the outcomes summarized in Table 1 pertain to outcomes at six months.

When electrodes are placed parallel, the success rates for achieving 50% relief of pain are slightly higher, but not significantly so statistically, when the diagnostic criterion is 80% relief of pain compared with 50% relief of pain. Nor are success rates significantly different for achieving 50% relief of pain if a single diagnostic block or two blocks are used.

What is apparent is that there are no published data on the proportions of patients who achieve 80% or complete relief of pain after treatment with electrodes placed perpendicularly. Individual patients who did achieve such outcomes can be found in the data of some studies [61] but are too few in number and occur in samples too small to produce clinically meaningful success rates.

Outcomes of 80% relief of pain, corroborated by improvements in function and use of other health care, have been reported only in studies that used 80% or 100% relief after two diagnostic blocks and that used parallel placement of electrodes. It is not evident from the literature if these higher-grade outcomes occurred *because* more demanding diagnostic criteria were used, or *because* electrodes were placed parallel, but the fact that studies that used perpendicular placements did not report high grades of outcome strongly suggests that they did not occur, or that they occurred in numbers too small to publicize.

Table 1. Summary statistics on the success rates (%) and [95% confidence intervals] of lumbar medial branch radiofrequency neurotomy

Procedural Technique		Perpendicular	Parallel				
Definition of successful outcome	100%					23 [20–26]	56 [47–65]
	80%					36 [32–40]	
	50%			64 [51–77]		58 [54–62]	
		26 [12–40]	57 [52–62]		49 [26–62]		
Diagnostic blocks	Criterion	50%	50%	80%	50%	80%	100%
	Number	1 block	1 block			2 blocks	

Success rates at six-month follow-up are plotted according to if electrodes were placed perpendicular or parallel to the target nerve, if one or two diagnostic blocks were used, if the diagnostic criterion was 50%, 80%, or 100% relief of pain, and whether outcome after treatment was 50%, 80%, or 100% relief of pain. Empty cells are ones for which there are no data in the literature.

Discussion

The present review differs from previous reviews in three respects. In the first instance, the evidence was not restricted to RCTs. In accordance with the principles espoused by Archie Cochrane [121], all the available literature was considered. Indeed, with respect to the effectiveness of lumbar RFN, observational studies were more informative than controlled trials. Whereas controlled trials may have reported that active treatment was, on average, more effective than sham treatment, or not more effective, few such trials provided data on how often treatment was effective to a clinically meaningful extent.

In the second instance, the evidence for lumbar RFN was stratified according to the selection criteria and the procedural technique used. In that regard, the null hypothesis raised for the study was refuted. Differences in patient selection and differences in technique make a difference to outcomes. Furthermore, in terms of GRADE, the evidence rates as high quality for many of the classes in the stratification.

In the third instance, success of treatment was not measured simply by statistically significant differences in group data, be they within studies or between studies. Rather, emphasis was laid on quantifying effectiveness in terms of the success rate of treatment. This parameter was used because it is meaningful and informative to physicians, their patients, and those who pay for the treatment. Success rates indicate how often the treatment is likely to generate a successful outcome. In turn, success rates inform patients of their chances of obtaining a successful outcome. Success rates directly generate cost-effectiveness information, simply by factoring the cost of each treatment into the denominator of the success rate.

This information is not provided by group data. Changes in mean pain scores of a group may be significant statistically, but they do not show if all patients benefit equally or if only some patients benefit; they do not show what the chances are of a particular patient getting a particular grade of outcome. Those questions require categorical data in the form of success rates. Ideally, all published studies would provide complete and transparent response data as recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [122], which is defined as the cumulative distribution function. Moving forward, this would greatly reduce ambiguity when completing similar systematic reviews. Consistent publication of procedural images would also reduce ambiguity.

For a given outcome measure, success might be defined as achieving the minimal clinically important change, or more demanding criteria can be applied, such as 50% improvement or 100% improvement. Debating exactly which definition should be used is immaterial if data are available for a spectrum of definitions. In that event, consumers can adopt the data that pertain to their preferred definition. In that regard, a clear picture emerges concerning the effectiveness of lumbar medial branch RFN.

The results of the present study provide a comprehensive summary of the effectiveness of lumbar medial branch RFN for a variety of definitions of success. Moreover, they show that effectiveness differs according to how patients are selected and how patients are treated. These results generate several implications that apply, with some degree of overlap, to physicians, to those who write reviews, and to payers.

Physicians can choose to select their patients using single, intra-articular blocks or medial branch blocks, and then use the perpendicular technique for RFN. Should they do so, the evidence shows that success rates will be relatively low, and no better than the results achieved by sham treatment or exercise therapy. Furthermore, there is no published evidence on long-term outcomes for this protocol, and no evidence on the effectiveness of repeat treatment.

Physicians can choose to use parallel placement of electrodes, knowing this technique has been shown to be superior to sham therapy in controlled trials [98,110]. Using one or two medial branch blocks, with 50% relief being the diagnostic criterion, success rates of 50–60% for achieving 50% relief of pain can be expected.

If physicians use a parallel technique and select patients based on 70–80% relief from two diagnostic blocks, they can expect success rates of 50–60% for 50% relief of pain, but also a 50% chance of achieving 80% relief and a 25% chance of achieving complete relief, along with improvements in function and decreased use of analgesics.

If the threshold for selection is raised to complete relief from comparative local anesthetic medial branch blocks, physicians and their patients can expect a 56% success rate for achieving complete relief of pain, accompanied by restoration of activities of daily living, and no need for further health care. If pain recurs as the targeted nerves regenerate, relief can be reinstated by repeat RFN.

Another consideration is that lumbar medial branch RFN is not a single treatment, as is surgery. The treatment does not cure the cause of pain; it only anesthetizes it. The treated nerves can regenerate. Therefore, the evidence from single applications of treatment cannot be portrayed as having no "long-term" effect when the treatment can readily be repeated when appropriate. Long-term effects are better measured according to the median duration of effect of the first application, as well as the success rates of subsequent applications.

The results of the present study show that there are differences in outcome according to how patients are selected and which RFN technique is used. Not all versions of RFN are the same technically or in what they achieve. Outcomes are clearly inferior, in terms of success rates and duration of relief, if single lesions are delivered by electrodes placed perpendicular to the target nerves or

placed using discredited procedural techniques. Some of these techniques have been shown to be no more effective than sham treatment, and for those who write reviews or influence health care policy, the inferior techniques cannot legitimately be used to impugn other techniques such as parallel electrode placement. The parallel technique has been shown to be more effective than sham treatment. Outcomes for the parallel technique do not significantly differ statistically when stratified based on patient selection, but the quality of outcome does. A 56% success rate for achieving 50% relief of pain is different from the same success rate for achieving complete relief of pain. Our review identified great heterogeneity in how successful outcomes are defined, which should be considered in the future.

Our review also identified great heterogeneity in how patients are selected and how lumbar medial branch RFN is performed even within the relatively strict confines of research. Pragmatically, there is likely even greater heterogeneity in how lumbar medial branch RFN is employed in clinical practice. In the current climate of value-based health care, both research and clinical outcomes from lumbar medial branch RFN may benefit from a more standardized approach. The results of this systematic review suggest that superior outcomes may be achieved with more rigorous patient selection via the use of two blocks, and optimal techniques may be achieved via the use of a parallel technique. Future research may determine additional means of optimizing patient selection and technique.

Conclusions

This systematic review stratified outcomes from lumbar medial branch RFN based on patient selection and techniques. There is significant heterogeneity in the available research. Effectiveness differs according to how patients are selected and how lumbar medial branch RFN is performed. The use of single blocks with a perpendicular technique results in inferior outcomes that may not be greater than sham treatments. In comparison, superior outcomes are evident with the use of two blocks and a parallel technique. Given the differences that appear when using this type of stratification, strong consideration toward these variables is warranted in future research and reviews.

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Multisociety Statement on *Effect of Radiofrequency Denervation on Pain Intensity Among Patients with Chronic Low Back Pain: The Mint Randomized Clinical Trials* by Juch *et al.*

November 21, 2017

Representatives of the undersigned twelve medical specialty societies, comprising physicians who prescribe and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, have convened to issue a statement on the recently published Mint Randomized Clinical Trials[1] from the Netherlands. These medical specialty societies share a common goal with patients and payers: identifying procedures that provide value to the patient and society through measurable improvements in pain and physical function with no or minimal adverse events. To this end, the undersigned societies think it is critical to repudiate the conclusions of the Mint Trials and support continued access to these invaluable procedures.

The MINT Trials are irredeemably flawed by study design, patient selection, procedural technique, and data analysis. Our critique below is specific to the facetogenic pain trial, but the criticisms also apply to the sacroiliac joint (SIJ) pain and the combination facetogenic/SIJ pain arms.

Study Design

A pragmatic comparative effectiveness trial should reflect usual practice. Radiofrequency (RF) neurotomy is only provided upon failure of conservative care, including exercise. The MINT Trial studies a choice no patient would face: an exercise program in conjunction with RF or an exercise program alone. Furthermore, in a stunning omission, there is no measurement of baseline pain or function prior to RF, following medial branch block (MBB). Hence the confounded trial is really: MBB, RF, and exercise versus MBB and exercise. Afterward, there are no useful data beyond three months, as any co-interventions (medications, RF, surgery) were allowed after that point. The value of RF neurotomy is its durability, unstudied here.

Patient Selection

It is paramount in a study assessing the effectiveness of an intervention in patients with a specific diagnosis that the patients selected *actually have* the diagnosis in question, and criteria for an accurate diagnosis of facetogenic pain exist. Contrary to this, the MINT Trial employed selection criteria lacking sufficient rigor. Consider that 931 study participants underwent single bilateral MBBs at L3-4, L4-5, and L5-S1; and an extraordinary 72% of them were reported to have a positive block response. This is *more than twice* the disease prevalence of facetogenic low back pain in any studied population. In addition, recall that nobody was treated for unilateral or for more localized back pain. Rather, all blocks and RF were *bilateral and multilevel* in this population with > 10 years of low back pain. Thus, the study participants were more likely chronic non-specific back pain patients than patients suffering from true facetogenic pain.

RF Technique

The study employed small-gauge electrodes, generating small lesions. Standard practice for RF neurotomy is to employ large-gauge electrodes to generate larger lesions, which are more likely to capture and ablate a larger portion of the target nerve. Just as important, the RF electrode placement technique is ambiguously described in the supplementary content and unreferenced,

and not described in the study. The authors' published protocol describes their plans to "submit images to an expert panel to assess correct needle placement." The results of any expert panel review have not been published, nor any images provided in the publication. The authors have possibly used an invalidated needle trajectory known to fail to adequately capture the target nerve[2]. There is serious doubt as to whether RF neurotomy was accomplished in this study population.

Data Analysis

Diverging from guidelines on reporting results of studies on spine pain treatments, the investigators' interpretation of the results relies solely on the between-group mean differences in outcomes data, rather than interpreting the outcomes based on the recommended assessment of each treatment's success or failure to achieve statistically significant and clinically meaningful change in response to treatment, and analysis of categorical outcomes comparing treatment success rates in each group. Without the results of these more appropriate analyses, the authors' conclusions remain unsupported. Of additional concern, patients lost to follow-up were omitted from analysis rather than accounted for as treatment failures. An intention-to-treat analysis was applied, but many participants did not receive their assigned treatment. Without an as-treated analysis, it is unclear how patients fared with the treatments they actually received. Unfortunately, the authors did not publish the study's primary data to allow further analyses and accounting for these glaring omissions in the published results.

A pragmatic RCT assessing the effectiveness of a therapeutic intervention is meaningful only when the intervention is performed on appropriately selected patients using documented anatomically accurate technique. RCT methodology has no value if the patients did not have the condition under investigation, the therapeutic procedure as performed lacks validity, the study design does not reflect real-life clinical choices, and the data analysis is flawed. As a result, we conclude that the MINT Trials provide no useful commentary on the well-established clinical effectiveness of RF neurotomy.

Current Best Available Evidence

Fortunately, several studies have been published that establish the effectiveness of RF neurotomy when performed according to standard practice -- using large-gauge electrodes with anatomically correct needle placement in patients with confirmed facetogenic pain. While, in practice, some physicians rely on 50% relief from a single medial branch block, studies establishing the effectiveness of RF neurotomy in treating facet pain should use more rigorous patient selection (i.e. dual comparative local anesthetics blocks) to limit the study population to those with facetogenic pain. In brief, sufficient pain relief following appropriately performed diagnostic medial branch nerve blocks determines patient selection for RF neurotomy. Low amounts of pain relief following a block, or a patient's response to a single diagnostic block, are unacceptable selection methods for study inclusion due to high false-positive rates. Specifically, the single block false-positive rate is between 25-45%, and this is significantly reduced by performance of a second comparative block.[3-10]

Two benchmark studies of RF neurotomy used appropriate patient selection and treatment technique; [11,12] selection was based on comparative local anesthetic blocks. Both studies achieved the best results heretofore reported in the literature. The first study reported 60% of patients maintaining at least 80% relief for 12 months.[11] The second study reported complete relief of pain for at least 6 months in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 15 months per treatment.[12]

The results of these two studies illustrate what can be achieved by RF neurotomy if performed correctly and in appropriately selected patients. An impressive 55-60% of patients experience at least 80% pain relief. **No other intervention of any kind, for any form of back pain, provides this size of effect at this level of success.**

American Academy of Pain Medicine (AAPM)
American Academy of Physical Medicine and Rehabilitation (AAPMR)
American College of Radiology (ACR)
American Pain Society (APS)
American Society of Anesthesiologists (ASA)
American Society of Neuroradiology (ASNR)
American Society of Regional Anesthesia and Pain Medicine (ASRA)
American Society of Spine Radiology (ASSR)
North American Neuromodulation Society (NANS)
North American Spine Society (NASS)
Society of Interventional Radiology (SIR)
Spine Intervention Society (SIS)

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OPEN ACCESS

Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group

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ABSTRACT

Background The past two decades have witnessed a surge in the use of lumbar facet blocks and radiofrequency ablation (RFA) to treat low back pain (LBP), yet nearly all aspects of the procedures remain controversial.

Methods After approval by the Board of Directors of the American Society of Regional Anesthesia and Pain Medicine, letters were sent to a dozen pain societies, as well as representatives from the US Departments of Veterans Affairs and Defense. A steering committee was convened to select preliminary questions, which were revised by the full committee. Questions were assigned to 4–5 person modules, who worked with the Subcommittee Lead and Committee Chair on preliminary versions, which were sent to the full committee. We used a modified Delphi method, whereby the questions were sent to the committee en bloc and comments were returned in a non-blinded fashion to the Chair, who incorporated the comments and sent out revised versions until consensus was reached.

Results 17 questions were selected for guideline development, with 100% consensus achieved by committee members on all topics. All societies except for one approved every recommendation, with one society dissenting on two questions (number of blocks and cut-off for a positive block before RFA), but approving the document. Specific questions that were addressed included the value of history and physical examination in selecting patients for blocks, the value of imaging in patient selection, whether conservative treatment should be used before injections, whether imaging is necessary for block performance, the diagnostic and prognostic value of medial branch blocks (MBB) and intra-articular (IA) injections, the effects of sedation and injectate volume on validity, whether facet blocks have therapeutic value, what the ideal cut-off value is for a prognostic block, how many blocks should be performed before RFA, how electrodes should be oriented, the evidence for larger lesions, whether stimulation should be used before RFA, ways to mitigate complications, if different standards should be applied to clinical practice and clinical trials and the evidence for repeating RFA (see table 12 for summary).

Conclusions Lumbar medial branch RFA may provide benefit to well-selected individuals, with MBB being more predictive than IA injections. More stringent selection criteria are likely to improve denervation outcomes, but at the expense of more false-negatives. Clinical trials should be tailored based on objectives, and selection criteria for some may be more stringent than what is ideal in clinical practice.

INTRODUCTION

There are few conditions in interventional pain medicine as controversial as lumbar facet joint pain. Everything from incidence, to diagnostic criteria, patient selection for interventions and the effectiveness of treatment is a source of contention and scientific debate. Regarding prevalence, the cited frequency of lumbar facet joint pain ranges from as low as 4.8% in the multicenter National Low Back Pain Survey evaluating final diagnoses of 2374 patients with low back pain (LBP) referred to an orthopedic or neurosurgical spine surgeon, to over 50% in systematic reviews on prevalence studies using varying criteria for diagnostic blocks performed by interventional pain physicians.[1–4] The wide disparity in reported prevalence raises questions regarding the accuracy of diagnostic testing in the absence of any non-interventional diagnostic reference standard. The poor correlation between facet joint pathology on imaging and LBP further fuels debate.[5] For diagnostic criteria, research and review articles abound on the ideal cut-off for designating a block as positive, and the optimal number of blocks that should be performed before lumbar facet radiofrequency ablation (RFA) treatment, with no consensus emerging.[6–11]

Lumbar facet interventions comprise the second most common procedure performed in interventional pain practices, with millions per year being performed in the USA alone.[12] For lumbar RFA, a recent review of the Marketscan commercial claims and encounters databases from 2007 to 2016 demonstrated a 130.6% overall increase in utilization (9.7% annually).[13] Along with increasing utilization, there was also a reciprocal increase in cost,

Table 1 Levels of evidence for guidelines and recommendations

Certainty of net benefit	Magnitude of net benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

with the cost per 100 000 enrollees increasing from US$94 570 in 2007 to US$266 680 in 2016 (12.2% annual increase). In addition, the high number of blocks is inconsistent with the most commonly cited prevalence rates, which are generally <15% in the non-elderly, but increase with age.[14 15] Increasing utilization alters the risk:benefit ratio of treatments; this, along with inconsistencies in practice, mixed results in mostly small heterogenous trials and the lack of widely accepted consensus guidelines has led to increased scrutiny and confusion on the part of government regulatory agencies and payers. The Spine Intervention Society (SIS; formerly the International Spine Intervention Society) has published guidelines on the performance of lumbar facet blocks and radiofrequency (RF) neurotomy,[16] but these rigorous criteria have not been followed in recent randomized controlled trials (RCTs),[17–19] and are not adhered to in domestic and international guidelines.[20–22] Whereas stringent selection criteria have been anecdotally associated with high RFA success rates,[23] the increased false-negative rate that inevitably accompanies strict diagnostic criteria,[7 14] and a host of other factors have resulted in an urgent need for guidelines to inform facet joint interventions in clinical practice and trials. These factors include the absence of safer and more effective alternatives for facetogenic LBP; the publication of large clinical trials that have been widely criticized for poor conduct, and rising utilization, which alters the risk:benefit ratio and calculations of cost-effectiveness.[12 24–27] Our aim is to develop pragmatic guidelines that can be used to guide clinical care, improve research quality and assist payers with clinical practice pathways and authorization decisions.

METHODS

The decision to convene a multispecialty working group to develop lumbar facet intervention guidelines was approved by the American Society of Regional Anesthesia and Pain Medicine Board of Directors on 20 November 2018. Stakeholder societies and other organizations (eg, Department of Veteran Affairs) with a vested interest in facet interventions were identified, and formal request-for-participation letters were sent to those societies, who all approved involvement in January 2019. Each society then nominated one or two members to serve on the committee based on their expertise, clinical experience and academic interests (see online supplementary appendix A for a list of participating societies and representatives). For the Department of Defense representative, the US Army Pain Medicine Consultant was selected, who has traditionally represented the Department of Defense in interagency and task force guidelines.[28]

The Lumbar Facet Intervention Guidelines Committee was charged with preparing guidelines on the use of facet blocks and RFA that span the entire spectrum of care to include patient selection, optimizing accuracy, interpreting results and risk mitigation. Questions and formats were developed by the committee chair based on input from the committee, and refined during conference calls. Guidelines for individual study questions were developed by subcommittees (modules) composed of four to five committee members, with one or two persons designated as the 'leads' responsible for task delegation. Once a module came to consensus on an answer, the committee chair assisted with editing and formatting, and the section was sent to the entire committee for open-forum comments and revisions. A modified Delphi method was used to tabulate comments, incorporate changes and converge the answers toward consensus over teleconference or electronic correspondence rounds. At the initial conference call, the committee decided that >50% panel agreement was sufficient to report a recommendation, but ≥75% agreement was required for consensus. After the task force completed the guidelines, the document was sent to the organizations' boards of directors for approval, with only minor changes permitted at this stage. For organizational agreement, we determined that consensus required at least ≥75% agreement, with dissensions tabulated for each individual question.

Search engines used during composition of the various sections included MEDLINE, Embase, Google Scholar and Cochrane Database of Systematic Reviews, in addition to examination of the reference sections of all manuscripts. There were no limitations on language or types of articles used to develop the guidelines, such that experimental studies were considered for the sections on physical examination and technical parameters, and case reports were considered for sections pertaining to risk mitigation and complications. Keywords used to address guideline topics were tailored to individual questions and included 'facet', 'low back pain', 'zygapophysial', 'zygapophyseal', 'radiofrequency', 'denervation', 'ablation' and 'arthritis'. Conclusions for each topic were graded on a scale from A to D, or as insufficient, according to the US Preventative Services Task Force

Table 2 What the grades of evidence mean and suggestions for practice

Grade	Definition	Suggestions for practice
A	Our committee recommends this treatment, test or strategy to improve outcomes. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	Our committee recommends this treatment, test or strategy to improve outcomes. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	Our committee recommends selectively offering or providing this treatment, test or strategy to improve outcomes to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	Our committee recommends against the intervention. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	Our committee concludes that the current evidence is insufficient to assess the balance of benefits and harms of the intervention. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the Recommendation Statement. If the treatment or service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Table 3 Levels of certainty regarding net benefit

Level of certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative populations with suspected lumbar facetogenic pain. The studies assess the effects of the treatment, test or other intervention on treatment or other relevant outcomes. The conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the intervention on outcomes, but confidence in the estimate is constrained by such factors as: ► The number, size, or quality of individual studies; ► Inconsistency of findings across individual studies; ► Limited generalizability of findings to individuals with suspected lumbar facetogenic pain; ► High likelihood of bias; ► Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and that change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on treatment and other outcomes of interest. Evidence is insufficient because of: ► The limited number or size of studies; ► Important flaws in study design or methods; ► Inconsistency of findings across individual studies; ► Gaps in the chain of evidence; ► High likelihood of bias; ► Findings not generalizable to individuals with suspected lumbar facetogenic pain; ► Lack of information on important outcome measures. More information may allow estimation of effects on treatment outcomes.

grading of evidence guidelines, with the level of certainty rated as high, medium or low (tables 1–3).[29] This system, which has been modified for use in interventional pain management guidelines drafted by the American Society of Regional Anesthesia & Pain Medicine, American Academy of Pain Medicine, American Society of Anesthesiologists, American Society of Interventional Pain Physicians (ASIPP) and the International Neuromodulation Society,[30–33] was chosen over others because of its flexibility,[34 35] which permits high-grade recommendations in absence of high-quality level I studies, which are challenging to conduct for invasive procedures.[36]

QUESTION 1: CAN HISTORY AND PHYSICAL EXAMINATION BE USED TO IDENTIFY A PAINFUL FACET JOINT, OR TO SELECT PEOPLE FOR PROGNOSTIC BLOCKS?

Overview

The diagnosis of lumbar facet joint pain relies on the combination of symptomatology, physical examination and confirmation by diagnostic block. Over the past several decades, numerous investigators have attempted to correlate physical signs and symptoms with facet pathology. Considering the high false-positive rate of uncontrolled facet blocks, and their inherent risks and costs, identifying likely responders is an important endeavor. Table 4 summarizes the studies discussed in this section.

Clinical studies evaluating the association of physical examination findings with facet block results

Fairbank *et al*[37] assessed range of motion in multiple directions, straight leg raising test and tenderness based on digital palpation in 25 patients with acute back and/or leg pain. Based on the site of maximal tenderness, the most painful area was chosen for an IA injection with 1.5 mL of local anesthetic (LA). A second injection was performed at a level randomly chosen among the nine remaining lumbar facet joints. A positive outcome was designated as subjective relief of symptoms. The patients who experienced pain relief with the verum injection had pain in the back and the upper thigh(s), whereas non-responders were more likely to have pain in their lower leg. A significant improvement in anterior-posterior and lateral movements was also observed in responders.

In a retrospective study by Helbig and Lee performed in 22 patients,[38] the authors sought to correlate response to an IA facet injection with diagnostic criteria that included pain in the back, buttock, leg or groin, signs of spasms or deformity, paravertebral tenderness, pain with motion and neurological examination. Back pain radiating to the groin or leg, pain worsened with extension-rotation and well-localized paraspinal tenderness were associated with a positive outcome, which was defined as prolonged relief lasting >6 months. Pain radiating below the knee was negatively associated with a positive response to facet blocks.

In a prospective study performed by Jackson *et al*,[39] IA facet joint injections with 1.5 mL LA and contrast were done on 454 patients with localized LBP with or without referral into a lower extremity, and a normal neurological examination. The authors studied the change in pain during 10 separate motions and examined 127 variables including tenderness. They found no significant correlation between provocative clinical examination signs and the outcome of the facet joint injection, although the absence of leg pain and pain aggravation with Valsalva maneuver were associated with positive response to the blocks.

Lewinnek and Warfield[40] performed a small, retrospective study in 21 individuals with refractory LBP, reporting their results with IA LA and steroid injections (1.5 mL) into the areas of maximal tenderness and pathology identified on X-rays. Patients were selected based on the presence of paraspinal tenderness and negative correlates for other etiologies, such as nerve root tension signs. They found no correlation between any historical or provocative examination sign and immediate or prolonged response to injections.

A prospective study by Lilius *et al*[41] assessed work and disability in 109 patients with LBP who had no signs of radicular pain following an IA injection with either cortisone and LA; a pericapsular injection of the same mixture; or an IA saline injection. They found that psychosocial factors significantly influenced outcome.

Table 4 Studies evaluating physical examination findings and facet block results

Study	Design/criteria for positive block	Interventions	Findings
Fairbank *et al*[37]	Prospective n=25 Subjective pain relief	IA (double blocks, one injection at symptomatic level, another at a random level)	Responders: pain in the back and thigh; straight leg raising test causes back pain. Non-responders: pain in the back and leg; straight leg raising test causes leg pain
Lewinnek and Warfield[40]	Retrospective n=21 Partial or complete pain relief with resumption of activities immediately and at 3 months	IA (single block)	Patients who had no other cause of LBP or sciatica and had a combination of facet degeneration, pain and tenderness, were more likely to initially respond to injection.
Helbig and Lee[38]	Retrospective n=22 Subjective pain relief from hours to months	IA (single block)	A 100-point scorecard was developed: Back pain with groin or thigh pain: +30 Well-localized paraspinal tenderness: +20 Reproduction of pain with extension-rotation: +30 Significant corresponding radiographic changes: +20 Pain below the knee: −10 Individuals with high scores (≥60) were likely to be responders but a low score could not reliably predict negative response to facet joint injections.
Jackson *et al*[39]	Prospective n=454 Difference in pre- and post-pain scores associated with lumbar motion	IA (single block)	There were no unique characteristics identified in patients who reported either no or increased pain after injection. However, the following factors correlated significantly with greater postinjection pain relief: older age, a history of LBP, no leg pain, pain not aggravated by Valsalva maneuver, normal gait, no muscle spasm and pain on extension after forward flexion.
Lilius *et al*[41]	Prospective n=109 Outcomes (subjective, work and disability) were assessed at 3 months	IA steroid/anesthetic, IA saline or pericapsular steroid/anesthetic (single block)	Inappropriate (non-organic physical) signs and symptoms and previous back surgery were associated with treatment failure.
Schwarzer *et al*[42]	Prospective n=176 ≥50% pain relief after a confirmatory block	IA or MBB (double comparative diagnostic blocks)	Neither clinical features (range of motion and straight leg raising test) nor pain referral patterns could predict response to diagnostic blocks. No patient with central/midline spinal pain responded to a confirmatory block.
Schwarzer *et al*[43]	Prospective n=63 ≥50% LBP reduction to bupivacaine block×3 hours but no response to placebo	IA and placebo (placebo controlled: normal saline to superficial muscle)	Similar history and examination features were seen in patients with or without facet joint pain.
Revel *et al*[44]	Prospective n=40 ≥75% LBP reduction	IA (single block)	Seven characteristics (Revel's criteria) were more frequent in patients with pain relief from facet blocks: older age; absence of pain exacerbation by coughing, absence of pain exacerbation by lumbar hyperextension, absence of pain exacerbation by forward flexion and rising from forward flexion, absence of pain exacerbation by extension-rotation and pain relieved by recumbency.
Revel *et al*[45]	Prospective, controlled n=80–42 who received lidocaine ≥75% LBP reduction	IA local anesthetic or placebo (IA saline)	The presence of at least five of the seven Revel's criteria (above) including pain reduction by recumbency resulted in 92% sensitivity and 80% specificity.
Manchikanti *et al*[50]	Prospective n=120 ≥75% pain reduction	MBB (double comparative diagnostic blocks)	The prevalence of clinical findings (pain better by sitting/lying, pain worsened by sitting/standing/walking/coughing/lumbar spine range of motion, positive straight leg raising test and pain referral pattern) were similar between positive and negative block groups. Back pain with straight leg raising was weakly associated with positive blocks.
Manchikanti *et al*[52]	Prospective n=180 ≥75% pain reduction	MBB (double comparative diagnostic blocks, lidocaine±Sarapin±steroid, bupivacaine alone)	Back or leg pain during straight leg raising was negatively associated with pain relief from facet blocks.
Manchikanti *et al*[51]	Prospective n=200 ≥75% pain reduction	MBB (double comparative diagnostic blocks)	A large number of individual clinical characteristics did not correlate with facet mediated pain diagnosed by double blocks.
Young *et al*[46]	Prospective n=23 An injection produced concordant pain and ≥80% pain reduction	IA (single block)	Absence of worsening LBP during rising from sitting was associated with a positive response to facet injections. Centralization of pain was associated with negative response to facet injections.
Laslett *et al*[47]	Prospective n=116 ≥75% pain relief or complete eradication of primary pain	IA or MBB (single block)	Revel's criteria had low sensitivity and high specificity; therefore, the authors concluded they are not appropriate for screening purposes. Age ≥65 years reached predictive significance with complete eradication of primary pain as a reference; no pain with cough/sneezing and no worsening of pain when rising from flexion approached predictive significance with ≥75% LBP relief as a reference.
Laslett *et al*[48]	Prospective n=120 ≥75% pain reduction stratified in 5% increments	IA or MBB (single block)	CPR consist of combinations of seven characteristics: age ≥50; pain is least when walking/sitting; paraspinal pain; modified somatic perception questionnaire >13; positive extension-rotation test and absence of centralization. When positive response to facet block is set at 95% pain reduction, four CPRs have 100% sensitivity, one CPR improved post-test probability by five-fold.
Cohen *et al*[54]	Retrospective n=192 Patient selection: ≥50% pain reduction RFA success: ≥50% pain relief×6 months	MBB (single block) RFA	RFA success patients were more likely to have paraspinal tenderness, whereas positive 'facet loading' (pain worsened by extension-rotation) and chronic opioid use were more prevalent in RFA failure patients.

Continued

Table 4 Continued

Study	Design/criteria for positive block	Interventions	Findings
DePalma *et al*[49]	Retrospective n=160–52 with lumbar facet joint pain ≥75% pain reduction	IA (double comparative diagnostic blocks)	Paraspinal low back pain had a sensitivity of 95% and specificity of 25%. Lack of paraspinal tenderness suggested the facet joints were unlikely to be the source of axial LBP. The diagnostic sensitivity of midline LBP is low for facet joint pain.
DePalma *et al*[15]	Retrospective, n=157–49 with lumbar facet joint pain ≥75% pain reduction	MBB (double comparative blocks)	Facet joint pain patients were more likely to be older than those with internal disc disruption, and more likely to be obese than those with sacroiliac joint pain.
Streitberger *et al*[55]	Prospective n=275 Patient selection: Pain relief ≥50%, but one block had to result in ≥80% benefit RFA success: ≥50% pain relief	MBB (double comparative diagnostic blocks with lidocaine and bupivacaine) RFA	Only depression was associated with a shorter duration of RFA success.
Conger *et al*[56]	Retrospective n=111 ≥80% concordant pain relief RFA success: ≥50% pain relief at 6 months	MBB (double comparative diagnostic blocks with lidocaine and bupivacaine) RFA	Older age and larger Cobb angle associated with RFA treatment success.
Cohen *et al*[57]	Prospective n=318 (63 with suspected facet joint pain) Patient selection: ≥50% pain reduction after a block RFA success: ≥50% pain relief×3 months	MBB (single block) RFA	Number of Waddell signs inversely correlated with treatment outcomes. Factors associated with treatment success included older age, shorter duration of pain, lower baseline pain scores and functional disability, absence of secondary gain and not having concomitant pain and psychiatric conditions. Among concurrent comorbidities, the presence of pelvic or abdominal pain and depression were most strongly correlated with negative outcome.

Double comparative diagnostic blocks refer to two separate blocks with lidocaine and bupivacaine.
CPR, clinical prediction rule; IA, intra-articular injection; LBP, low back pain; MBB, medial branch block; RFA, radiofrequency ablation.

Schwarzer *et al*[42] conducted a prospective study attempting to identify presumptive clinical features in 176 patients with chronic LBP using double, comparative LA injections or MBBs. In the 15% of patients who achieved concordant pain relief with lidocaine and bupivacaine, none of the 16 physical signs or symptoms evaluated was associated with a positive response.

In a smaller prospective study Schwarzer *et al* conducted in 63 patients,[43] one or more IA injections of LA produced pain relief in more patients than did injection of saline (32% vs 40%). None of the historical features or clinical tests discriminated between patients diagnosed with facet joint pain and those who had negative blocks.

Following up on a prospective study that examined the association between 90 physical examination signs and symptoms and IA LA injections,[44] Revel *et al*[45] performed a placebo-controlled crossover study in 80 patients based on the presence of five of seven criteria they found in their first study: age >65 years, absence of exacerbation with coughing, relief with recumbency, pain not worsened by forward flexion or rising from forward flexion and pain not exacerbated by hyperextension or extension-rotation. Patients were divided into positive (n=43) and negative (n=37) groups based on whether they had at least five of the previously identified seven criteria. Patients randomly received one block, an IA injection with 1.5 mL of lidocaine and contrast, or saline and contrast into the lowest two or three joints in double-blind fashion. A positive response was ≥75% pain relief after LA block. The presence of at least five of the seven criteria (ie, the positive group) had 90% sensitivity and 80% specificity for identifying patients with a positive response to lidocaine.

In a prospective study involving 81 patients with chronic lumbar or lumbopelvic pain who underwent IA facet joint blocks, discograms and sacroiliac (SI) joint injections, Young *et al*[46] sought to identify predictive factors for response to diagnostic injections. Although the group could identify several predictive factors for SI joint and lumbar discogenic pain, the only characteristics associated with a positive IA facet block were lack of pain provocation when rising from sitting, and absence of pain centralization.

In a study involving 116 patients with LBP who underwent comparative LA IA injection or MBB, Laslett *et al*[47] tried to confirm the value of Revel's criteria.[44] They found that these criteria were associated with low sensitivity (<17%) but high specificity (90%), with only absence of pain by coughing or sneezing reaching predictive significance. The authors concluded that these tests were a poor screening tool to select patients for facet interventions, which require high sensitivity. In a subsequent attempt to better refine clinical prediction rules in 120 patients with LBP,[48] the same authors performed double blocks, stratifying responses into 5% intervals from 75% pain relief to >95% relief. At cut-off values <90%, no clinical findings predicted positive response to facet injections. Using a cut-off value of 95%, the authors found that a negative extension-rotation test, absence of pain centralization, age ≥50 years, pain relief with walking, pain relief with sitting, paraspinal onset and a score on the Modified Somatic Perception Questionnaire suggesting somatization were predictive of facetogenic pain.

DePalma *et al*[49] performed a retrospective study in 160 patients (170 axial LBP episodes) that attempted to determine whether the pattern of LBP was associated with the source. The presence of paramedian pain significantly increased the likelihood of SI joint pain and dual MBB-confirmed facet joint pain, while a predominance of midline symptoms was positively associated with internal disc disruption. In a companion study by the same group in 153 patients with axial LBP (157 pain episodes),[15] older age and higher body mass index were more likely to be associated with a diagnosis of facet joint pain compared with internal disc disruption and SI joint pain, respectively.

Two studies by Manchikanti *et al*[50 51] containing 120 and 200 patients, respectively, who presented with axial LBP with or without radiation to the lower extremity, found that neither historical nor physical examination findings correlated with comparative MBB-confirmed lumbar facet joint pain. In the larger study,[51] the authors were not able to confirm the criteria delineated by Revel *et al*.[45] In this study, the presence of paraspinal tenderness was associated with non-significant trend toward being predictive of a positive response (p=0.188). In the smaller study, back pain elicited by straight leg raising

was weakly associated with a positive block.[50] The diagnostic criteria in these studies were ≥75% concordant pain relief with comparative LA MBB. A third study from the same group aimed to analyze the duration of effect of dual MBB with LA and LA with either steroid or Sarapin in 180 patients. The only factor that was predictive for a negative outcome was back or leg pain with straight leg raising; none of the other clinical features had a significant correlation with block results.[52]

Dolan *et al*[53] performed a clinical study in 58 people with clinically diagnosed lumbar facet pain, subjecting them to single photon emission computed tomography(SPECT) and IA steroid injections. SPECT-positive patients (n=22) experienced better outcomes through 3 months than SPECT-negative patients (n=36), but tenderness was not associated with response to injections.

Clinical studies evaluating the association of physical examination findings with RFA results

Several studies have examined factors associated with RFA treatment outcomes. Although not every patient with facetogenic pain will respond to denervation, the high false-positive rate of uncontrolled blocks and the lack of any confirmatory reference make RF responders an excellent population to use for predictive modeling. In the first study to evaluate factors predictive of lumbar facet RFA outcomes in 192 patients from three different hospitals, Cohen *et al*[54] found that paraspinal tenderness was associated with a positive outcome, while 'facet loading' (pain worsened by extension-rotation) was predictive of a negative outcome. In a smaller, prospective study conducted in 44 patients who underwent RFA after a concordant response to comparative LA MBB, Streitberger *et al*[55] found no association between radiating pain and treatment response; in bivariate analysis, only depression was found to be associated with a shorter duration of treatment response.

More recently, a retrospective review performed in 111 patients who responded with ≥80% concordant pain relief after comparative LA MBB found that older age and a smaller Cobb angle were associated with ≥50% pain reduction 6 months after RFA.[56] Finally, in a large, prospective study that sought to determine factors associated with interventional treatment outcomes in 318 patients with LBP (63 with suspected facetogenic pain), Cohen *et al* found that 51.1% of individual with 0 Waddell signs, 34.1% with one or two signs, 26.1% with three or four signs and only 16.7% of people with five of five Waddell signs experienced a positive treatment outcome. Other variables associated with treatment success included older age, shorter duration of pain, lower baseline pain scores and better function, absence of secondary gain and not having concomitant pain and psychiatric comorbidities.[57]

Experimental studies

Experimental studies in cadavers have shed light on movements associated with lumbar facet joint stress. In one of a series of experiments designed to determine conditions under which the facet joint capsules were stretched, Ianuzzi *et al*[58] found that in the upper three facet joints, the greatest strain and joint displacement was associated with lateral bending. In the lowest two joints, the largest degree of strain occurred during forward flexion.

Systematic reviews and guidelines

Petersen *et al*[59] performed a systematic review to establish clinical diagnostic rules for various LBP etiologies. For lumbar facet joint pain, the only findings predictive of a negative response to double diagnostic IA injections or MBBs were the absence of relief with recumbency, and the lack of pain centralization.

Finally, guidelines on facet blocks do not support positive physical examination requirements. A systematic review performed by designated members of ASIPP concluded that conventional clinical findings were unreliable in identifying painful lumbar facet joints.[60] A similar view had been previously espoused in guidelines by the SIS, which designated diagnostic injections as the only reliable means for diagnosis.[16]

Recommendations

In summary, there are no pathognomonic physical examination or historical signs that can reliably predict response to facet joint blocks in individuals with mechanical chronic LBP, although pain that is not predominantly in the midline, and possibly tenderness overlying the facet joints, appear to be weakly associated with a positive response to facet joint interventions. The previous studies that found no association between physical signs and symptoms for the most part did not evaluate this metric. Studies have also shown that maneuvers associated with radicular signs (eg, pain worsened by coughing, pain radiating below the knee) may be predictive of negative diagnostic facet blocks. Similar to other interventions for chronic pain, greater disease burden and psychiatric comorbidities may be associated with definitive treatment failure. When selecting targets for blocks, levels should be determined based on clinical presentation (radiological findings when available, tenderness on palpation performed under fluoroscopy, pain referral patterns); grade C evidence, low level of certainty.

QUESTION 2: IS THERE ANY CORRELATION BETWEEN RADIOLOGICAL FINDINGS AND A PAINFUL FACET JOINT OR RADIOFREQUENCY ABLATION OUTCOMES, AND SHOULD IMAGING BE REQUIRED BEFORE PROGNOSTIC BLOCKS?

Imaging techniques have been used to identify radiological markers of painful lumbar facet joints. In previous studies, response to IA facet joint injections or MBB has served as the gold standard for confirming that potentially painful lumbar facet joints identified radiologically were sources of LBP. The most widely investigated imaging modality used to detect potentially painful facet joints is SPECT, a nuclear medicine imaging technique that requires intravenous administration of a gamma-emitting radioisotope and involves considerable radiation exposure compared with conventional X-rays. Using external detectors, two-dimensional projections are acquired in multiple planes and reconstructed to form a three-dimensional image. The quantity of emissions detected from the radionuclide provides a measure of biological activity; thus, SPECT scans can identify active inflammation involving facet and other joints. Scintigraphy is a similar technique that also requires administration of a gamma-emitting radioisotope and uses external detectors, but only a two-dimensional image is generated. Previous studies in which SPECT, scintigraphy or CT were used in conjunction with confirmatory IA facet joint injections or MBB have reported mixed results regarding their correlation and predictive value.[53 61–68] Table 5 summarizes the studies discussed in this section.

SPECT and confirmatory MBB

In a randomized, double-blind placebo-controlled trial, 29 patients with LBP completed the research protocol.[62] In this study, all patients received a SPECT scan after which a pain

Table 5 Studies evaluating the association between imaging pathology and facet joint block and treatment outcomes

Study	Design	Number of subjects	Results	Comments
Holder *et al*[63]	Prospective study designed to evaluate the sensitivity and specificity of PS or SPECT scans in identifying patients responsive to IA facet injections	43 patients (male=17, female 26) Mean age 55 years (range 16–18 years)	PS group: sensitivity=0.71, specificity=0.76, (+) predictive value=0.38, (–) predictive value=0.93 SPECT group: sensitivity=1.0, specificity=0.71, (+) predictive value=0.41, (–) predictive value=1.0	The authors concluded that the high sensitivity and (–) predictive value made SPECT scan a valuable screening tool before invasive facet injections. Other symptomatic abnormal areas of tracer uptake were identified in 37% of patients.
Schwarzer *et al*[67]	Single-blind, placebo-controlled trial designed to evaluate the effects of CT-confirmed facet osteoarthritis on IA facet joint injections	63 patients Median age 59 years (IQR 51–68); Female:male ratio 3:1 Median LBP duration 7 years (IQR 2–20)	32% (95% CI 20 to 44) with ≥50% pain reduction at 3 hours following IA placebo injection 40% (95% CI 27 to 53) with ≥50% pain reduction at 3 hours following IA LA injection No significant group differences in CT joint scores based on patient response to IA placebo or IA LA injections	CT not recommended in the diagnostic evaluation of facet pain.
Dolan *et al*[53]	Prospective comparison of IA facet joint injections between patients with SPECT (+) and SPECT (–) scans	SPECT (+) group=22 SPECT (–) group=36	Significant improvement in VAS and McGill pain scores in SPECT (+) group at months 1 and 3 94% SPECT (+) group reported improvement at month 1 compared with 47% in SPECT (–) group	No significant improvements evident at month 6 47% of SPECT (+) patients had osteoarthritic facet joints compared with 18% of SPECT (–) group.
Pneumaticos *et al*[66]	Prospective comparison of IA facet joint injections between patients with SPECT (+) and SPECT (–) scans	SPECT (+) group=15 SPECT (–) group=16 No SPECT comparison group=16	Significant improvement in pain at months 1 and 3 in SPECT (+) group vs SPECT (–) and no SPECT comparison groups Number of facet joints treated in SPECT (+) group reduced from 60 to 27 with cost savings of US$326/patient	No significant group differences at month 6.
Cohen *et al* [69]	Retrospective, multicenter study examining factors associated with cervical medial branch RFA outcomes	92 patients, 44 with significant facet pathology on MRI	57% success rate in overall cohort, 52% in individuals with significant MRI pathology (p=0.75)	Slightly higher success rate in the younger patients (ie, with less facet joint pathology) treated at Walter Reed may have contributed to findings.
Cohen *et al*[54]	Retrospective, multicenter study examining factors associated with lumbar medial branch RFA outcomes	192 patients, 117 with significant facet pathology on MRI	54% success rate in overall cohort, 52% in individuals with significant MRI pathology (p=0.75)	Slightly higher success rate in the younger patients (ie, with less facet joint pathology) treated at Walter Reed may have contributed to findings.
Ackerman and Ahmad[61]	Randomized, double-blind trial of MBB vs IA facet joint injections in patients with SPECT (+) scans	IA facet injection group=23 (male=14, female=9) MBB group=23 (male=12, female=11); Median age=39.3 years Mean symptom duration=7.6 weeks	61% had ≥50% pain relief at week 12 in IA facet injection group vs 26% in MBB group 26% Sensitivity/specificity of SPECT in the IA facet joint injection group 0.79 and 0.70, respectively Pain rating and ODI scores significantly less in the IA facet group vs MBB group at week 12	All patients in the IA facet injection and MBB groups received lidocaine and triamcinolone.
Stojanovic *et al*[68]	Retrospective review of correlations between MRI and outcomes of MBB and RF denervation	127 consecutive patients Male=52% Mean age=52.9 years	Facet joint degeneration or hypertrophy on MRI significantly correlated with ≥50% pain reduction following MBB but not RF Younger patients significantly more likely to fail MBB but not RF	Prospective studies recommended to confirm study findings.
Koh *et al*[65]	Prospective comparison of MBB between patients with SPECT (+) and SPECT (–) scans	SPECT (+) group=28 (male=12, female=16); SPECT (–) group=5 (male=2, female=3) Mean age SPECT (+) group=60.4 Mean age SPECT (–) group=51.8 years	85.7% with >50% pain reduction at week 2 in SPECT (+) group vs 20% in the SPECT (–) group 78.6% with >50% pain reduction at week 4 in SPECT (+) group vs 0% in the SPECT (–) group No significant between-group differences in ODI	All MBB performed with ultrasound guidance using lidocaine and triamcinolone.
Freiermuth *et al*[62]	Randomized, double-blind, placebo-controlled trial to determine the sensitivity/specificity of SPECT/CT to identify patients with facet joint pain prior to IA facet injections	29 patients (male=16, female=13) age range=38–83 years	SPECT/CT; sensitivity 0.57 (95% CI 0.18 to 0.90), specificity 0.77 (95% CI 0.55 to 0.92) Diagnostic accuracy=0.72 (ideal value 1.0)	SPECT/CT not recommended as first-line diagnostic tool prior to IA facet joint injections.
Jain *et al*[64]	Randomized, double-blind, controlled trial of SPECT/CT to identify patients most likely to respond to comparative LA low back injections (sacroiliac joint, facet joint)	SPECT/CT group=7 Control group (no SPECT)=14	71% with ≥50% pain reduction in SPECT/CT group vs 43% in the control group (p<0.05) immediately following MBB	Included patients with chronic LBP. Most common diagnoses were sacroiliitis, followed by L4-5 and L5-S1 facet arthropathy.
Sawicki *et al*[70]	Retrospective study to determine if PET/MRI could predict MBB responders	10 patients with mechanical neck pain. 140 joints assessed. 6 joints in 6 patients had increased uptake of radioactive tracer and facet arthrosis, and 27 joints had arthrosis without increased uptake	The six patients with positive PET and MRI scans had better outcomes immediately after blocks, and through 3-month follow-up	Used 3 mL of LA and steroid per level.

IA, intra-articular; LA, local anesthetic; LBP, low back pain; MBB, medial branch block; MRI, MRI resonance imaging; ODI, Oswestry Disability Index; PET, positron emission tomography; PS, planar scintigraphy; RF, radiofrequency; RFA, radiofrequency ablation; SPECT, single photon emission computed tomography; VAS, visual analog scale.

clinician, blinded to the results of the SPECT scan, examined each patient. Based on the results of the clinical examination, the patient received a series of three fluoroscopically guided MBB with 0.5 mL of lidocaine 2%, 0.5 mL of bupivacaine 0.5% or a placebo injection of 0.5 mL of sodium chloride 0.9%. The order of injected substances was randomized and the clinician was blinded to the injectate. The definition of a positive response to a lidocaine or bupivacaine block was ≥70% pain reduction or a numerical pain rating of <3 on an 11-point scale. The entire series of three blocks was considered to be negative if >50% pain reduction was reported following a placebo injection. Following completion of the three blocks, the SPECT scans were reviewed. The series of three blocks was repeated for individuals who had a negative series of blocks but had a positive SPECT scan for

a joint that was not blocked. Following completion of the first series of blocks, 24% (7 of 29) of patients had a positive response and 76% (22 of 29) had a negative response. Among individuals who had positive blocks, 4 of 7 also had positive SPECT scans (sensitivity=0.57), and 17 of 22 (specificity=0.77) had negative SPECT scans. A second series of blocks was performed in six patients, two of whom had a positive response. Although a power analysis was not performed, the authors concluded that SPECT should not be recommended as a first-line diagnostic tool prior to MBB.[62]

In a second study, a randomized, double-blind controlled trial was conducted that involved 80 patients with LBP.[64] Patients were randomized to receive SPECT scans prior to diagnostic blocks (SPECT scan group, n=40) or no scan prior to receiving blocks (control group, n=40). The block recommendations of patients randomized to the SPECT scan group was modified based on the scan results, but block recommendations for patients randomized to the group who did not receive a scan were based solely on clinical evaluation. For patients diagnosed with facet pain at the L4-L5 or L5-S1 levels, fluoroscopically guided MBB were performed using 0.6 mL of LA. A positive block was defined as ≥50% pain reduction 4 hours after the block was completed. In the SPECT scan group, 7 of 40 patients were diagnosed with facet arthropathy, while 14 of 40 patients in the control group had a similar diagnosis. In the SPECT scan group, 71% (5 of 7) had a positive MBB compared with 43% (6 of 14) in the control group. The between-group response rate to MBBs was statistically significant ($p<0.05$).[64]

In a third study, an observational, open-label design was used to compare the outcomes of MBB in patients with chronic LBP (n=30) with and without facet joint-positive SPECT scans.[65] The primary outcome measure was >50% pain reduction on the visual analog scale (VAS) at weeks 2 and 4 following the MBB. A secondary outcome measure was the Oswestry Disability Index (ODI) score. All MBB were performed using ultrasound guidance, and the injectate consisted of 2 mL of lidocaine 1% and triamcinolone 30 mg. At week 2 follow-up, 85.7% (24 of 28) of patients in the SPECT scan-positive group reported >50% pain reduction compared with 20% (1 of 5) in the SPECT-negative group. At week 4 follow-up, 78.6% (22 of 28) in the SPECT-positive group reported >50% pain reduction compared with none (0 of 5) in the SPECT-negative group. No significant group differences in ODI scores were reported.[65]

SPECT and confirmatory IA facet joint injections

Two prospective, open-label studies compared the effects of IA facet joint injections in patients with facet joint-positive and joint-negative SPECT scans. In the first study, a randomized open-label design was used to investigate the effects of IA facet joint injections in patients with facet joint-positive and joint-negative scans.[66] Patients with LBP (n=47) were randomized in a 2:1 ratio to receive a SPECT scan prior to fluoroscopically guided IA facet injections (group A) or no scan prior to IA injections (group B). Patients randomized to group A who had positive SPECT scans were further categorized as group A1, and patients with negative SPECT scans were categorized as group A2. The primary outcome measure was change in pain scores at months 1, 3 and 6 following the injections. All facet joint injections were fluoroscopically guided, and the injectate consisted of 2.5 mL of bupivacaine 0.5% and 0.5 mL of betamethasone (total dose of 3 mg). At 1-month follow-up, the change in pain scores was significantly greater ($p<0.008$) in group A1 (n=15) compared with group A2 (n=16) and group B (n=16). Similarly, at month 3 follow-up, the change in pain scores was significantly greater ($p<0.001$) in group A1 compared with group A2 and group B. A greater proportion of patients in group A1 (87%, 13 of 15) reported improvement in pain at 1-month follow-up compared with group A2 (13%, 2 of 13) and group B (31%, 5 of 16). In patients randomized to group A1, the number of facet joints injected decreased from 60 indicated by the referring physician to 27. This translated to a cost-per-patient reduction, based on Medicare reimbursement rates, from US$2191 to US$1865, inclusive of imaging costs.[66] Follow-up cost-effectiveness studies have yet to be conducted, and calculating cost-effectiveness depends on many factors including patient selection, interpretation of imaging, designation of outcomes and local cost variances, among others.

In the second study, 58 patients with a clinical diagnosis of facet joint pain received SPECT scans; 22 had facet joint-positive scans and 36 had joint-negative scans.[53] Outcome measures at months 1, 3 and 6 included the VAS pain score, Present Pain Intensity score and the modified McGill Pain Questionnaire (MPQ). All IA injections were performed using fluoroscopic guidance, and the injectate consisted of 1 mL of lidocaine 1% and methylprednisolone 40 mg. At 1-month follow-up, patients with SPECT-positive scans experienced significantly greater reductions ($p<0.05$) in VAS pain scores compared with patients with SPECT-negative scans. Similarly, at 1-month and 3-month follow-ups, patients with SPECT-positive scans experienced significantly greater reductions (month 1, $p=0.005$; month 2, $p=0.001$) in MPQ scores compared with patients with SPECT-negative scans. Compared with patients with SPECT-negative scans, a significantly greater proportion of patients with SPECT-positive scans reported improvement at 1-month (94% vs 47%; $p<0.0005$) and 3-month (79% vs 42%, $p<0.001$) follow-ups.[53]

SPECT and confirmatory IA facet joint injections versus MBB

A randomized, double-blind trial was performed to compare the effects of IA facet joint injections (n=23) and MBB (n=23) at 12-week follow-up in patients with chronic LBP who had lumbar facet joint-positive SPECT scans.[61] The primary outcome was ≥50% pain reduction on the numeric rating pain scale at 12 weeks. A secondary outcome was the ODI score. All injections were performed using fluoroscopic guidance, and the injectate for the IA facet joint injections and MBB consisted of 0.1 mL of lidocaine 1% and 0.2 mL of triamcinolone (total dose 2 mg). At the 12-week follow-up visit, 61% (14 of 23) experienced ≥50% pain reduction in the IA group compared with 26% (6 of 23) in the MBB group. The sensitivity and specificity of a facet joint-positive SPECT scan in the IA group were 0.79 and 0.70, respectively. No significant group differences in ODI scores were reported.[61]

SPECT, planar scintigraphy and confirmatory IA facet joint injections

A prospective open-label design was used to investigate the sensitivity and specificity of SPECT compared with planar scintigraphy for identifying patients likely to respond to IA facet joint injections.[63] A consecutive series of patients with a clinical presentation suggestive of facet pain (n=43) received planar scintigraphy and SPECT scans. All patients received fluoroscopically guided IA facet joint injections with bupivacaine and steroid. The follow-up time periods were not specified. Forty-one patients were included in the sensitivity and specificity analyses. The sensitivity and specificity of planar scintigraphy for identifying IA injection-confirmed facet pain were 0.71 and

0.76, respectively. The positive predictive and negative predictive values were 0.38 and 0.93, respectively. For SPECT, the sensitivity and specificity were 1.0 and 0.71, respectively, and the positive and negative predictive values were 0.41 and 1.0, respectively.[63]

MRI, therapeutic facet injections and radiofrequency denervation

In a retrospective study, facet joint pathology was categorized in 127 patients and correlated with MBB and RF denervation outcomes.[68] A positive MBB was defined as ≥50% pain reduction concordant with the duration of the LA, and a positive RF outcome was defined as ≥50% pain relief at month 3 follow-up. The presence of facet joint degeneration or hypertrophy correlated with a positive response to MBB (71% vs 51% in individuals with normal facet joint morphology; p=0.04), but no correlation was observed between facet joint pathology and RF outcomes. Younger age was correlated with a negative response to MBB (p=0.04), but no significant correlation was found between younger age and RF outcomes.[68]

Cohen *et al* performed studies in the lumbar (n=192) and cervical (n=92) spine regions designed to determine factors predictive of RFA outcome. In both studies, no association was found between the presence of significant facet joint pathology on MRI and denervation results.[54 69]

Finally, a small retrospective study performed in 10 patients with chronic neck pain sought to determine whether positron emission tomography (PET)/MRI could be used to identify patients for therapeutic cervical MBB performed with high volumes of LA and steroid.[70] Increased 18F-fluoro-deoxyglucose uptake along with facet arthrosis was observed in six joints in six patients. These patients exhibited better pain relief 3 hours after the blocks, which persisted through 3-month follow-up.

CT and confirmatory IA facet joint injections

In a single-blind, placebo-controlled trial, 63 patients underwent CT scans followed by a series of IA facet joint injections at the L3-L4, L4-L5 and L5-S1 levels.[67] The CT scans were independently reviewed in random order by three radiologists blinded to the clinical status of the patient. Each facet joint was scored (0–3 scale) based on the extent of joint space narrowing, sclerosis, subchondral erosions, cysts and osteophytes. All facet joint injections were fluoroscopically guided and the injectate consisted of up to 1.5 mL of bupivacaine 0.5%. The placebo injections consisted of 0.5 mL of normal saline. A positive IA injection was defined as a ≥50% reduction in VAS scores maintained for a minimum of 3 hours. A positive response to placebo injections was observed in 32% (20 of 63) of patients, and 40% reported a positive response to the bupivacaine injections. No significant association was observed between radiological grading of facet joint pathology and response to IA facet joint injections.[67]

Recommendations

In summary, there is moderate evidence supporting the use of SPECT for identifying painful lumbar facet joints prior to MBB (grade C recommendation, moderate level of certainty). Weak evidence exists supporting the use of SPECT for identifying painful lumbar facet joints prior to IA facet joint injections (grade D recommendation, low level of certainty). Regarding the cost-effectiveness of SPECT, further study is required. For scintigraphy, MRI and CT, there is weak or no evidence supporting the use of these imaging modalities for identifying painful lumbar facet joints prior to MBB or IA facet joint injections (grade D recommendation, low level of certainty).

QUESTION 3: SHOULD PHYSICAL THERAPY AND/OR PRIOR CONSERVATIVE TREATMENT BE A PREREQUISITE BEFORE PROGNOSTIC FACET BLOCKS? IF SO, FOR HOW LONG SHOULD THEY BE CONTINUED, AND SHOULD THEY BE CONCURRENT?

Rationale for conservative care, and duration of care, before facet blocks

Existing clinical practice guidelines (CPGs) for LBP consistently recommend care that is patient-centered, screens for psychosocial factors, provides back pain education and promotes exercise and physical therapy (PT).[21 71–74] As a result, the timing and duration of LBP treatments remain highly individualized. If primary care and acute care providers follow guideline recommendations, patients will present to pain specialists already having trialed many conservative treatments. Since adherence to these guidelines is poor,[75 76] pain specialists should confirm whether or not conservative treatment was received before considering invasive treatments. It is important to note that the order of treatment is not based on studies showing better outcomes with conservative care; rather, it is based on the fundamental medical principal of starting with less invasive treatments even when more invasive options may be more efficacious.

The North American Spine Society coverage guidelines recommend failure of at least 3 months of conservative therapy (defined to include exercise, PT, chiropractic care and/or analgesics) before consideration of diagnostic facet joint blocks and nerve ablation.[77] Accordingly, insurance authorizations for facet joint interventions increasingly mandate a trial of conservative management prior to authorization of the procedure.[78] Despite consistent evidence of only small effect sizes for conservative treatments (including PT) in chronic LBP,[79 80] proponents still recommend conservative care trials due to their relatively lower costs and risks. This position appears to be supported by interventional pain researchers since the inclusion criteria within prospective studies of facet joint interventions usually,[18 19 81–83] but not always,[84 85] include a preceding trial of conservative treatment. Yet, there is no existing evidence that demonstrates the appropriate timing or optimal duration of conservative treatments for chronic LBP.

Rationale for continued or concurrent conservative care and PT and clinical trials

A common rationale for combined therapy is that therapeutic interventions can reduce pain and create an opportunity to engage in exercise and other healthy behaviors, and ultimately motivate patients toward self-care. Although this is common in clinical practice, few studies have examined the role of combination therapies. A recent high-profile randomized trial compared exercise for LBP with exercise with RF denervation of the facet joints and reported no significant difference in average improvement in pain intensity between groups.[17] However, clinically meaningful improvement was only observed in the group that received exercise plus RF denervation of the facet joints.[24] Additional evidence is available from the broader spine intervention literature. For example, Cohen *et al*[86] compared cervical epidural steroid injections, conservative treatment (ie, PT and/or adjuvants) and combined treatment, and found that combination therapy provided better improvement in several outcomes than either stand-alone treatment. One explanation provided by the authors for these findings was that the intermediate-term benefit

afforded by injections created a therapeutic window in which the effectiveness of PT could be maximized. International guidelines also support multimodal and interdisciplinary treatment, with recently published guidelines from the National Institute for Health and Care Excellence[87] and the Belgian Federal Healthcare Institute[88] recommending lumbar facet RFA as part of an interdisciplinary care pathway for LBP. In addition to physician-prescribed treatments, self-care strategies for low back health that should be implemented or continued include exercise, smoking cessation, weight loss, healthy diet, mood and stress management and sleep hygiene.[89 90]

Recommendations

We recommend a 3-month trial of different conservative treatments before facet joint interventions. Conservative therapies may include medications (eg, non-steroidal anti-inflammatory drugs, antidepressants), physical treatments (exercise, heat or cold therapy, massage), integrative treatments (acupuncture, spinal manipulation if indicated) and others (nutrition, weight loss, sleep hygiene). Although current research does not provide clear answers regarding the optimal timing of facet joint blocks for chronic LBP, or the appropriate duration of conservative care before consideration of facet interventions, prospective studies of facet joint interventions have generally required a trial of conservative treatment before study enrollment. This is consistent with the recommendations of multiple CPGs; grade C recommendation, low level of evidence.

QUESTION 4: IS IMAGE GUIDANCE NECESSARY FOR LUMBAR FACET BLOCKS AND RADIOFREQUENCY ABLATION?

Theoretical concerns: accuracy and safety

Image guidance has become an essential component of performing spinal procedures in pain management.[91] For MBB and IA facet joint injections, fluoroscopy and to a lesser degree, CT guidance are most commonly used. The use of imaging allows accurate needle placement ensuring the lowest volume of anesthetic is administered, thereby reducing spread to surrounding tissues which may lead to false-positive test results. Image guidance also improves safety through direct visualization of bony elements of the neuraxis, thus avoiding structures in proximity including pleura, neural foramina and vascular supply. An often-cited study evaluating the accuracy of 45 nonimage-guided paravertebral somatic nerve blocks found that in only 18% of cases was contrast confined to the paravertebral area. Epidural spread was noted in 70% of injections.[92] In addition, a case report in an active duty service member described a spinal headache requiring an epidural blood patch following a blind lumbar facet block.[93]

Guidelines and insurance coverage

The SIS guidelines state 'fluoroscopy is mandatory for the conduct of lumbar medial branch blocks' as it provides an overview of the bony anatomy as well as the ability to confirm contrast spread.[16] For MBB, the nerve is not directly visible with fluoroscopy, but its location is inferred based on accepted landmarks. Fluoroscopy is also a familiar technology that most pain providers are comfortable with. Nevertheless, fluoroscopy—and particularly CT—have considerable costs associated with them, including purchase price, maintenance and dedicated facilities. Furthermore, both modalities expose patient and provider to radiation, which may have cumulative health effects.

Guidelines released by the US Department of Health and Human Services in 2008 asserted that radiographic guidance is typically employed during facet injections to ensure accurate needle placement and to avoid unnecessary injury.[94] In 2018, Noridian, a major carrier for the Centers for Medicare and Medicaid Services, provided a local coverage determination for Medicare that asserted facet joint interventions must be performed under fluoroscopic or CT guidance and that interventions performed under ultrasound would not be reimbursed.[95] Multiple insurance companies have pursued similar requirements, including BlueCross BlueShield,[78] Cigna[96] and UnitedHealthcare,[97] determining that facet blocks performed without fluoroscopy (ie, using ultrasound only) were medically inappropriate.

Validity and accuracy of fluoroscopic and CT-guided blocks

Fluoroscopy is the gold standard for facet blocks and is recommended or required by multiple insurance companies.[78 96 97] With regard to MBB, although a randomized study in the cervical spine found the incidence of 'missed nerves' to be 7% using fluoroscopic guidance with 0.25–0.5 mL of injectate,[98] an earlier study performed in 15 healthy volunteers reported that a 0.5 mL injectate bathed the target lumbar medial branch in 100% of 120 nerve blocks.[99] For lumbar IA injections, studies have reported high rates of failed blocks, ranging between 29% and 38% per joint using fluoroscopy.[18 100] However, the precise anatomical osseous resolution afforded by CT imaging may yield higher success rates. In one retrospective study, Weininger *et al* reported a 94% success rate for 85 lumbar IA facet blocks.[101] Success rates exceeding 90% have been reported by other investigators as well.[102]

Despite its high-resolution compared with plain radiographs, the use of CT blocks for MBB and RFA has not been demonstrated in randomized clinical trials. For MBB, CT precludes the use of real-time contrast injection or digital subtraction angiography to detect intravascular uptake. Regarding RFA, the use of CT is limited because of imaging constraints and radiation exposure. Fluoroscopy allows for the placement of electrodes in an orientation parallel to the nerve, whereas this is less likely with CT. In one cadaveric study (n=10) that compared fluoroscopy with CT for RF neurotomy in the lumbar spine, the use of CT was associated with less overlap of the electrode with the medial branch (ie, was oriented less parallel), more instances (30%) where the electrode was positioned proximal to the medial branch and two cases (10%) where the ventral ramus was inadvertently reached.[103] The authors concluded that in current practice, CT should not be used for thermocoagulation of the lumbar medial branches.

Use of ultrasound in the lumbar spine

The use of ultrasound may provide an alternate imaging modality for performance of MBB and IA injections. This modality has widespread acceptance in regional anesthesia and can visualize soft tissue anatomy, neural structures and vascular supply.[104 105] In addition, ultrasound is portable, can be used in pregnancy and does not require use of protective garments. However, there are disadvantages of using ultrasound for lumbar spine interventions, including limited visualization of the field, lengthy learning curve and potential for inadvertent vascular uptake, which can be reliably detected using real-time contrast injection or digital subtraction angiography.[106] Furthermore, needle visibility can be impaired by body habitus and depth to target.

Use of ultrasound for lumbar medial branch blocks

Greher *et al* performed 50 bilateral ultrasound-guided lumbar facet nerve injections on five cadavers.[107] The target point was the groove of the cephalad margin of the transverse process of the L1-L5 vertebrae (T12-L4 medial branches) adjacent to the superior articular process. After needle placement with ultrasound, axial transverse CT scans were performed with and without contrast. Forty-five of the 50 needle tips were located at the target point, with the remaining five needle tips within 5 mm of the target. The authors reported 94% accuracy, but noted contrast spread in the paraforaminal region in 14%, epidural spread in 10%, and intravascular spread in 4% of cadavers.

In a similar three-part study, Greher *et al* performed an ultrasound-based anatomical analysis on one fresh, non-embalmed cadaver to define necessary landmarks, views and estimated distances.[108] In the second part of the study, delineation of sonographic landmarks was tested in vivo in 20 healthy volunteers for the L2–L4 medial branches. Using this information, the authors performed 28 ultrasound-guided MBB in five patients who had suspected bilateral lumbar facet joint pain, an average body mass index (BMI) of 23 kg/m^2 and an average age of 36 years. Fluoroscopy was used to confirm localization. Based on dissection, needle position was correctly located at all three levels in the cadaver. In the volunteers, landmarks were reported as good in 19 patients and sufficient in 1 patient with obesity. In the five patients with suspected lumbar facetogenic pain, 25 of 28 needles were determined to be accurately placed, with the remaining three needle tips within 5 mm of the target. Of note, the L5 dorsal ramus was not blocked.

In a retrospective study, Han *et al* compared ultrasound-guided and fluoroscopically guided lumbar MBB for lumbar facet joint pain in 214 patients.[109] Among the 146 patients for whom follow-up information was available, no differences were noted between groups for complications, pain reduction and functional improvement through 6-month follow-up. However, the performance time for ultrasound-guided MBB was shorter.

Wu *et al* screened 103 RCTs and non-RCTs comparing the effectiveness of ultrasound guidance with fluoroscopically or CT-guided injection techniques for lumbar facet joint pain.[110] Among these trials, three were included involving 202 patients. The authors found no significant difference between groups for pain scores, functional capacity or procedure time. They concluded that ultrasound-guided injections were feasible and reduced radiation exposure.

Use of ultrasound for lumbar IA facet injections

In a two-part study, Galiano *et al* performed 50 ultrasound-guided lumbar facet joint injections on five cadavers to assess the feasibility and accuracy of this modality.[111] The authors reported that 8 of 50 attempts were not feasible due to reduced visibility from trapped air during cadaver conservation; however, for the 42 approaches performed, only 2 were outside the joint space. Ultrasound and CT showed the same mean depth and lateral distance to the reference point. Pearson's correlation coefficient was 0.86 ($p<0.001$) between ultrasound and CT, including the two failed measurements. In a follow-up study, the same group enrolled 40 patients in a trial comparing ultrasound with CT-guided lumbar facet joint injections.[112] Among the 20 patients in the ultrasound group, 16 had clearly defined anatomic landmarks and 100% accurate needle placement was achieved. In two patients with BMI >28 kg/m^2, the lumbar facet joints could not be clearly visualized. The authors concluded that both groups showed benefit, but that procedure time and radiation exposure were less in the ultrasound-guided group.

Gofeld *et al*[113] published an ultrasound-guided lumbar facet joint injection study using fluoroscopy as a control. IA facet joint injections were performed on five cadavers using an in-plane ultrasound approach. For the 50 injections performed, IA contrast spread was clearly observed in 44 cases. In the other six injections, however, contrast flow was noted in the surrounding soft tissue. In four of the six failed injections, the facet joint was not visible on ultrasound imaging. Using a similar approach, Ha *et al*[114] retrospectively compared the outcomes of 105 patients with lumbar spinal pain who received fluoroscopically guided (n=51) and ultrasound-guided (n=54) IA facet blocks. Both groups demonstrated similar pain relief, functional improvement and complication rates through 6-month follow-up, but costs and procedure time were slightly higher for the ultrasound-guided procedures. Flaws in this study include the retrospective nature of the study, the absence of information regarding technical success rate, and the relatively low prevalence of obesity in the cohort (the Korean population in which this study was conducted has a lower prevalence of obesity than in non-Asian populations).

Limitations of ultrasound

One of the chief limitations for ultrasound guidance in lumbar spinal procedures is reduced visibility of the neuraxis in patients with obesity. As the prevalence of obesity in the USA approaches 40%,[115] the utility of this approach would be limited in a large portion of the population. Rauch *et al* evaluated use of ultrasound in 84 MBBs performed in 20 patients with a BMI exceeding 30 kg/m^2.[116] The authors found that while visualization was sufficient to identify anatomical targets with ultrasound, the success rate was only 62%. Most failed blocks occurred at L5, which innervates the most commonly clinically affected facet joint, due to poor visibility from surrounding adipose tissue and artifacts from the iliac bone and sacral ala.[117] In order to overcome some of the limitations of targeting the L5 dorsal ramus with ultrasound, an oblique out-of-plane technique in a rotated across axis view has been proposed. In a cadaveric study (10 cadavers with significant degenerative spondylosis, 20 L5 blocks), Greher *et al* reported an overall success rate of 80%; when the five cadavers with moderate-to-severe spondylolisthesis were excluded, there was a 100% success rate in the 10 blocks.[118]

A second drawback of ultrasound is the possibility of targeting the wrong segment without fluoroscopic confirmation, which is potentially problematic at upper lumbar vertebrae. For example, a study performed in the thoracic spine found that misidentification of the targeted spinal level occurred between 16% and 43% of the time depending on the scanning technique, with <50% accuracy in patients with obesity.[119] Consequently, when mid-lumbar and upper lumbar levels are targeted, care must be taken to count up from the sacrum, or down from the lowest thoracic level, ensuring the identification of individuals with transitional anatomy (eg sacralized L5) which may theoretically increase the likelihood of lumbar facetogenic pain.[120]

Another consideration is the lack of studies assessing ultrasound-guided RFA of the lumbar medial branches. A proof-of-concept cadaveric study was performed by Gofeld *et al* examining the use of a magnetic positioning system and ultrasound guidance for lumbar medial branch RF neurotomy.[121] When using this visualization system with internally cooled electrodes, the ultrasound-guided procedural accuracy rate reached 97%, with one failed placement at the L5 dorsal ramus. Of note,

four of six L5 dorsal ramus injections required an out-of-plane caudad-to-cephalad approach because of acoustic interference produced by the iliac crest. It is important to recognize that internally cooled electrodes were used for this study, which do not require the steep caudad-cephalad angulation necessary to position the electrodes parallel to the neural target (cooled electrodes are placed perpendicular to the target).

Recommendations

We recommend that CT or preferably fluoroscopy (lower costs, faster time and less radiation exposure than CT) be used for lumbar MBB, although ultrasound may be useful in patients in whom radiation exposure may be associated with potential harm (eg, pregnant), or in patients without obesity when radiographic or radiological imaging is unavailable; grade B recommendation, moderate level of certainty. For IA injections, we recommend the use of CT scanning to enhance accuracy, although fluoroscopy using contrast injection to confirm IA placement can also be considered in certain cases (eg, a thin person without minimal joint narrowing) given the lower costs and radiation exposure; grade C recommendation, low level of certainty. For lumbar medial branch RFA, we recommend that fluoroscopy be used, as the inaccuracies with placement and additional radiation exposure from CT compared with fluoroscopy preclude any theoretical benefit; grade B recommendation, low level of evidence.

QUESTION 5: ARE FACET BLOCKS 'DIAGNOSTIC', 'PROGNOSTIC' OR BOTH?

Premise of diagnostic facet interventions

The terms *diagnostic*, *prognostic* and *predictive* are commonly used interchangeably in the chronic LBP literature, although they are not the same. *Diagnosis* refers to the 'process of identifying a disease, condition or injury from its signs and symptoms'.[122] *Prognosis* most commonly refers to the forecasting of the likely course of a disease (which may include the effects of treatment), while *predictive* provides specific information about the likely effect of a therapeutic intervention. Whereas these terms may overlap in some scenarios, they refer to different concepts.

Diagnostic injections can be used to isolate the anatomical structures that are the source of pain. They are a critical but potentially flawed element in the practice of pain and spine medicine. The lack of a clear and accepted historical or physical examination finding, diagnostic test and/or spine imaging finding indicative of pain of facetogenic origin (ie, a reference standard) results in reliance on these indirect methods of diagnosis. Although the administration of LA into the joint itself or on the nerves supplying the facet joint with diagnostic intent has face validity, it is based on the assumption that there are no other factors (ie, activity, natural course, psychological stress) that will alter the pain, and relies on the patient's report of pain relief, which is subject to bias and cannot be independently verified.[123] Therefore, the possibility of false-positive or false-negative reporting is an inherent risk with facet blocks that can only be identified through placebo injections (for false-positive) and careful control of confounding factors.

Limitations of diagnostic injections

The limitation of facet interventions in providing diagnostic information is confounded by the placebo response, which is robust for procedures.[124 125] The placebo response experienced by the patient receiving either IA facet joint injections or MBB should never be interpreted to mean the patient is not experiencing pain of pathophysiological origin. However, the placebo response is, without question, a factor in some percentage of patients reporting pain relief after diagnostic blocks. How clinicians approach patients prior to or after the procedure undoubtedly affects how prevalent and robust the placebo response is. Furthermore, one cannot discount the effect that LAs may have either on surrounding tissue or possibly systemically, if given in sufficient volume. As stated previously, placebo injections may help sort out some of the placebo response, although there are ethical issues to consider. It is important to note that even placebo injections may not entirely address the placebo response, as sham interventions (eg, the injection of saline into a joint after superficial anesthetic) may actually exert a therapeutic effect in some people.[36]

The accuracy of a diagnostic block is contingent on several technical and anatomical factors. First, it assumes the procedure is performed in manner that results in anesthesia of the intended, but not unintended, structure(s).[14] MBBs are unlikely to achieve this level of specificity due to the close proximity of the intermediate and lateral branches of the dorsal rami, resulting in non-selective neural blockade.[14 99] Second, a successful diagnostic block assumes that the anesthetized nerve supplies a single anatomical target and that the ensuing pain relief results from anesthetization of only that structure. In the case of an MBB of the dorsal primary ramus, this is not the case since it also innervates the multifidus muscle, interspinal muscle and ligament and periosteum of the neural arch.[126] An appropriately performed IA facet joint injection, in which the LA remains within the joint capsule, would theoretically meet this specificity assumption. Third, for an injection to have diagnostic or construct validity assumes that the diagnostic target (the facet joint) receives single-source innervation. Kaplan *et al*[127] found that one in nine patients (11%) who underwent image-guided MBB did not experience relief from experimentally induced facet pain from capsular distention. The authors stated that this could indicate a false-negative rate as high as 31%, and the result supports other studies finding aberrant facet joint innervation.[128] A similar argument has been made for the lack of diagnostic validity of lateral branch blocks in the context of diagnosis of SI joint pain.[129] MBBs do not meet these expectations; therefore, an MBB may more accurately be referred to as a test block.[130] An IA facet joint injection, in which the LA is contained within the joint, does meet the assumptions; therefore, it could be classified as a diagnostic intervention. However, practically, there is a high rate of failed IA injections ranging between 29% and 38% per joint, and 46% and 64% per patient.[18 100]

Limitations of prognostic injections

Prognostic injections can be used in risk stratification and treatment planning. Prognosis is closely aligned in medicine to predictability. A patient may appropriately ask his/her clinician, "What are the chances that I will get 50% pain relief from this intervention?" Similarly, a patient may ask, "What is my prognosis or expectation if I get 70% relief from the diagnostic block and then undergo radiofrequency denervation?" These are not easily answered questions. Evidence-based medicine may provide outcome estimates from interventions, but this is not the same as providing a prognosis or prediction.

IA joint and medial branch injections have been used to assess the probable response of medial branch and dorsal primary ramus RFA. The rationale is that if MBB relieves pain, then a treatment capable of physically interrupting conduction along the same nerve(s) should provide comparable relief, but last longer depending on the expected duration of disrupted signaling (ie,

until nerve regeneration or reinnervation occurs). The use of these interventions as a surrogate measure for outcome prediction carries the same limitations as their use as a diagnostic tool. The accuracy of a prognostic test also depends on how success or failure is defined. For instance, success of RFA might be expressed simply as pain relief at the point in time at which the LA is no longer active and the patient has recovered from procedural pain (days or weeks), or it could be defined as alleviation of pain at some predesignated distant time point (months) following the procedure. Depending on the time period chosen, the prognostic power of the initial intervention will be different.

The accuracy of prognostic interventions depends on the accuracy of diagnosis, including identification of the anatomic structure responsible for the pain and the correlation between the prognostic injection and treatment effect, which in turn is contingent on the efficacy of the procedure. The use of MBB as a prognostic tool for medial branch denervation outcome has very high face validity; however, the risks of false-positive and false-negative results negatively impact the quality of prediction.[123] The use of the lumbar facet joint injection as a prognostic injection for medial branch ablation carries the same limitations as the use of an SI joint injection to predict response from lateral branch ablation,[129] although unlike for SI joint pain, extra-articular (eg, ligamentous) facet joint pathology is uncommon.

Evidence for diagnostic and prognostic utility

The prevalence of facet joint pain has an exceptionally wide range of 5%–90% when using history, physical examination and radiological examination for diagnosis.[131] In light of the lack of objective measures of facet-mediated pain, MBB and IA facet joint injections with LA remain the most widely accepted approach to diagnosis, and a surrogate measure for prognosis. In a randomized trial assessing the effect of superficial LA and saline infiltration on double lumbar MBB and IA injections, a diagnosis of facet pain (≥75% pain relief 30 min postinjection) was conferred in 12% and 13% of patients with paraspinal tenderness, respectively.[132] Of note, the positive block rate increased significantly on the second diagnostic injection in individuals who received saline infiltration from the skin down to the facet joints or medial branches, but not those who received LA tissue infiltration. In those who received superficial tissue infiltration with LA but no facet or MBB, the percentage of positive blocks was higher after the first injection than the second (73% vs 12%). These findings support other findings that suggest that LA treatment of myofascial pain significantly contributes to false-positive blocks.[133]

In a multicenter case-control study by Cohen *et al*[134] which treated 511 patients with axial LBP who underwent RFA following either MBB, IA blocks or IA injections followed by MBB, the authors found a higher success rate with MBB than IA with injections (70.3% vs 60.8%). MBB remained a significant predictor for positive treatment response even when controlling for confounding factors. In the subsequent randomized, three-arm FACTS study by Cohen *et al*,[18] the authors found a false-positive rate of 30% when defined as significant pain relief following a lumbar MBB with saline. The proportions of positive responders to RFA in the IA and medial block diagnostic groups were 51% and 56%, respectively. Those treated who did not experience prolonged pain relief from saline medial branch injection had a positive response rate of 24%. This indicates that IA injections and MBB were significantly more prognostic than saline when long-term placebo responders were excluded.

Two studies have sought to evaluate the correlation between pain relief during a diagnostic MBB, and pain relief after RFA. In a prospective study by Cohen *et al*[6] performed in 61 patients who underwent lumbar RFA after MBB, the authors reported no difference in denervation success rates between 10% incremental cut-off intervals ranging from 50% to 100% relief after prognostic blocks, although patients who underwent ablation after experiencing <50% pain relief fared worse. In a retrospective analysis by Holz and Sehgal[135] conducted in 112 patients who experienced positive comparative LA MBB before lumbar and cervical RFA, the authors found no significant correlation between pain reduction after MBB and RFA.

Few studies have calculated the predictive value of lumbar MBB before RFA. In a retrospective review by Derby *et al*[9] in 229 patients who underwent single or double lumbar MBB with bupivacaine, the authors reported a sensitivity of 55%, a specificity of 77%, a positive predictive value of 78% and a negative predictive value of 53%.

Recommendations

IA facet joint injections meet criteria for diagnostic interventions for facet-mediated pain but are less predictive than MBB for response to medial branch RFA and are characterized by a high technical failure rate. As diagnostic tools, MBBs suffer from limitations related to aberrant lumbar facet joint innervation. Compared with saline controls, both IA and medial branch injections with LA provide better predictive information for medial branch RFA; grade B recommendation, low level of certainty.

QUESTION 6: ARE MEDIAL BRANCH BLOCKS PREFERABLE TO INTRA-ARTICULAR INJECTIONS TO SELECT PATIENTS FOR RADIOFREQUENCY ABLATION?

It has previously been written that lumbar MBB and IA injections are comparable in identifying painful facet joints, and selecting patients for RFA.[60 136 137] However, this assertion is based on two small studies,[138 139] neither of which preselected patients with screening facet blocks (ie, few likely had facetogenic pain) or performed RFA (ie, there is no predictive value), and only one of which assessed pain relief shortly (<1 hour) after the blocks.[138]

Pathophysiological and anatomical considerations

The argument supporting MBB over IA injections before RFA might appear to be intuitive. This is supported by an experimental study performed in 18 healthy individuals, 15 of whom experienced pain during facet joint capsular distention and returned for the second and third study phases.[127] In these individuals, five received saline injections while 10 received LA blocks of the two medial branches innervated by their initially injected joint. In the nine subjects who received LA MBB in whom intravascular uptake was avoided, eight could not feel repeat capsular distention, while all five subjects who received saline MBB perceived pain with capsular infiltration. This suggests that approximately 11% of individuals who receive technically successful MBB will continue to experience pain from facet joint pathology, which the authors attributed to aberrant, non-medial branch innervation.

Technically, MBBs are easier to perform and less painful than IA injections, which have a documented technical failure rate ranging between 29% and 38% per joint, and from 46% to 64% per procedure.[18 100] Since excessive procedure-related pain is a potential cause of false-negative blocks, a less painful procedure might be associated with a lower false-negative rate, though this has not been studied.[14] The technical failure rate for IA injections is highest at L5-S1, which is the most common clinically

Table 6 Studies and reviews comparing lumbar medial branch blocks and intra-articular injections as prognostic tools before denervation therapy

Study	Design/Study type	Number of patients	Diagnostic interventions	Results	Comments
Birkenmaier *et al*[145]	Randomized	41, 26 (13 in each group) who had a positive block and received cryodenervation	MBB with 1 mL bupivacaine or pericapsular injections with 2 mL before lumbar facet cryodenervation	MBB>IA at 6 weeks and 3 months	Differences favoring MBB non-significant at 6 months.
Cohen *et al*[134]	Case-control	511 who under MBB (n=212), IA (n=212) or MBB and IA (n=87) before RFA	MBB with 0.5–0.75 mL LA or IA with 0.5–1 mL LA+steroid	MBB>IA or MBB+IA at 3 months	In patients who received double-blocks, MBB>IA+MBB≥IA.
Cohen *et al*[18]	Two-phase, randomized	228 who underwent prognostic blocks, 135 who received RFA	0.5 mL MBB with LA and steroid, 0.5 mL IA injection or saline injection	Both MBB and IA >saline through 6 months, but no difference between MBB and IA injections	Those in the MBB and IA groups with a (+) prognostic block received RFA, while everyone in the saline group was treated.
van Zundert *et al*[142]	Narrative review	7 randomized studies, 349 patients	Indirect comparison of studies using IA and MBB blocks as screening tests before RFA	MBB>IA as screening test before lumbar facet RFA	Did not perform meta-analysis.
Practice Guidelines, Bogduk, ed[16]	Guidelines	Not noted	Indirect comparison of studies using IA and MBB blocks as screening tests before RFA	MBB>IA as screening test before lumbar facet RFA	Based on lack of validation for IA injections.

IA, intra-articular; LA, local anesthetic; MBB, medial branch block; RFA, radiofrequency ablation

affected facet joint (L4-5 is the most frequently radiologically degenerated joint).[43 117 140 141] In contrast, lumbar MBB rarely (<2%) miss the targeted nerve,[99] although intravascular uptake, which occurs in between 4% and 19% of injections, can lead to false-negative results.[106 142 143] In the study by Kaplan *et al*.[127] evaluating the ability of MBB to anesthetize facet joints, among the six subjects in whom intravascular uptake was appreciated, three were still able to perceive pain during capsular distention despite repositioning the needle to avoid intravascular contrast uptake. This indicates that false-negatives may occur from intravascular uptake even with real-time contrast injection.

Previous guidelines

In the relative absence of large, prospective studies comparing the prognostic value of IA and MBBs before RFA, experts have relied on indirect comparisons to draw conclusions, which are fraught with limitations. After reviewing the results of randomized trials based on the type of prognostic block, van Zundert *et al* concluded, 'Based on the evaluation of studies, IA injection of LA no longer can be recommended as a diagnostic test for prediction of response to RF treatment'.[142] In a review, Cohen *et al*[14] cited aberrant innervation, higher procedure-related pain and technical difficulties in recommending MBB over IA blocks as an RFA screening procedure. According to the Greater Manchester EUR Policy Statement on Facet Injections, released in October 2018 by the UK's National Health Service in Greater Manchester, 'facet injections for low back pain are no longer commissioned', and "all patients who are suitable for RF denervation should be considered for a diagnostic medial branch block'.[144] In 2012 guidelines from ASIPP, the authors concluded there is evidence to support the diagnostic utility of MBB, but fail to mention IA injections. Finally, in the SIS practice guidelines on lumbar MBBs, the organization concluded that '… MBB should replace IA injections for the diagnosis of lumbar zygapophysial joint pain'.[16]

Evidence from clinical studies

Three published studies to date compare the predictive values of MBB and joint injections before ablative therapy (table 6). In a case-control study by Cohen *et al*[134] involving 511 patients who received RFA after either IA blocks, MBBs or both blocks, the authors reported a higher success rate with MBB than with IA injections (70.3% vs 60.8%), which remained a significant outcome predictor in multivariable analysis. Birkenmaier *et al*[145] performed a randomized trial in 26 individuals (out of 41) with a positive facet block comparing the prognostic value of pericapsular lumbar facet injections with 2 mL of LA against MBB with 1 mL. Those who received MBB fared better for pain throughout the 6-month follow-up, with the difference between groups reaching statistical significance at 6 weeks and 3 months. A major flaw in this study is that pericapsular injections, unlike technically successful low-volume IA blocks, lack diagnostic specificity and face validity. Finally, in a two-phase study designed to determine the therapeutic efficacy of lumbar MBB and IA injections and their predictive value before RFA, Cohen *et al*[18] found no difference in RF outcomes through 6-month follow-up in the 93 people who proceeded to denervation after positive prognostic blocks. However, there was a significant difference in some outcomes when both groups were compared with the 42 people who received saline control blocks before ablation, which persisted for the duration of the study.

The diagnostic value of IA injections was called into question by a blinded, triple crossover study comparing IA lumbar facet injections with LA (verum), normal saline (placebo) and extra-articular needle placement (sham).[146] Schütz *et al*[146] found that the differences between response rates, defined as ≥2-point reduction in back pain, between the different groups was clinically and statistically non-significant, with slightly more responders in the verum group than in the placebo group, which in turn was associated with a marginally higher response rate than in the sham group. Overall, the authors concluded that a single IA injection was not a valid means to detect a painful lumbar facet joint.

Recommendations

Overall, we conclude that MBB should be the prognostic screening test of choice before lumbar facet RFA. IA injections of corticosteroids may, however, be of therapeutic value for certain populations in which there is suspected inflammatory facetogenic pain, and in whom denervation may be relatively contraindicated. In these cases, they may concomitantly serve as prognostic blocks. These individuals may include the young, athletic person in whom denervation of the multifidus and other spinal muscles (eg, intertransversarii, longissimus, iliocostalis) may result in muscle atrophy that can adversely impact their condition (eg, spondylolisthesis) or activities of daily living,[147 148] and individuals who may be at risk for complications with RF treatment (eg, pacemaker-dependent patients and those with automatic

implantable cardioverter-defibrillators).[149 150] Although RFA has been successfully employed in individuals with implantable devices, we are aware of at least two cases of a defibrillator discharging despite following precautions (personal communication from LTC Ron White (ret), Travis Air Force Base). Younger individuals may be more likely to present with acute inflammatory facetogenic pain, which has been shown in one small randomized trial to be responsive to IA steroids,[61] and to have a lower technical failure rate (ie, less osteoarthritic changes that can impede joint entry); grade C evidence, moderate level of certainty.

QUESTION 7: WHAT IS THE EFFECT OF SEDATION ON THE ACCURACY OF DIAGNOSTIC OR PROGNOSTIC INTRA-ARTICULAR FACET JOINT BLOCKS AND MEDIAL BRANCH BLOCKS?

Background for the use of sedation for diagnostic or prognostic injections

The use of sedation before diagnostic facet blocks is a subject of substantial debate. This controversy is predicated on the question of whether sedating and/or providing analgesic medications will alter the patient's 'true' response to the intervention. We will refer to procedural sedation in the manner it is commonly used as the provision of a sedative and/or an analgesic (eg, benzodiazepine and/or opioid, respectively), not based on the physiological response to the medication. The 'true' response to the injection is one that helps inform the physician in making the diagnosis or determining the likely prognosis from therapeutic interventions. The diagnostic or prognostic value of these blocks is discussed in a different section and will not be revisited here.

Sedation for these procedures has been justified using a patient-centric perspective (by decreasing procedure-related discomfort or anxiety) to reduce the risk of a false-negative response, as well as from a physician perspective (to increase patient satisfaction with the procedure, decrease body movements that can make the procedure difficult to complete, decrease the chance that the patient does not show up for the RFA and expedite workflow).[151–153] Although these benefits may exist, the use of sedation can also increase the false-positive rate and therefore have a negative effect on the diagnostic or prognostic accuracy of these procedures.[117] Benzodiazepines produce skeletal muscle relaxation and amnesia, which may result in a false-positive response (ie, alleviate baseline back pain).[154] Although they are not analgesics, they have been found to reduce pain tolerance, which may in turn reduce the pain relief associated with the procedure (false-negative response).[155] Fentanyl is an analgesic and could potentially accentuate the pain-relieving effect of the facet injection, resulting in false-positive results. Any sedative or opioid may interfere with postblock activity levels, thereby providing a spurious reflection of benefit.

Direct evidence: sedation for MBBs or IA injections

No studies were identified.

Indirect evidence: sedation prior to medial branch injections

Several studies published by the same group of investigators purported to examine the effects of sedation on the diagnostic validity of blocks; however, no postblock outcome measures were included in any group (table 7).[156–159] Sedation was achieved with saline in up to half of the individuals,[159] and the authors concluded that saline, midazolam or fentanyl can all produce false-positive results, with fentanyl>midazolam>saline. However, these studies suffer from many methodological flaws, including the lack of power estimation, absence of a clinically relevant group of patients receiving the benzodiazepine in combination with the opioid and a biased patient sampling that included a high proportion of opioid users and individuals with prior spine surgery. The authors also excluded any patient who did not respond to 'therapeutic' MBBs, which likely selects for placebo responders. Importantly, the authors did not assess the effect of sedation on postblock pain relief, but instead assessed sedation and pain relief before and after the drugs were administered. The authors did, however, assess the effect of sedation on the ability to perform previously painful maneuvers, and found that midazolam, fentanyl, and saline all resulted in sufficient ability to perform these movements.[159] The lack of difference is likely due to insufficient sample size.

Indirect evidence: sedation for diagnostic interventional pain and spine injections

One study examined the effect of sedation on SI joint and lumbar sympathetic injections using a randomized crossover study design.[160] In the primary crossover analysis, procedures done with light sedation using midazolam and/or fentanyl had a higher probability of a positive diagnostic block using ≥50% pain relief as the cut-off (OR 2.2; 95% CI 1.07 to 4.46; p=0.031) or ≥80% (OR 3.0; 95% CI 1.32 to 6.98; p=0.009). A similar increase in the positive rate of the diagnostic block was noted for the parallel and omnibus (all sedation vs all no sedation) analyses. Sedation decreased procedure-related pain but did not affect satisfaction scores or 1 month outcomes. Although this study did not directly address the question of the influence of sedation on diagnostic or prognostic facet intervention outcomes, it supports the conclusion that the validity of diagnostic injections can be affected by the use of sedation.

A retrospective study by Erdek *et al* examining predictive factors associated with celiac plexus neurolysis in 50 individuals with cancer pain supports this contention. Among those who did not receive sedation during the prognostic block done with LA, 73% experienced a positive outcome after neurolysis, which favorably compared with a 39% success rate in individuals who received intravenous sedation.[161]

Indirect evidence: sedation for pain-relieving procedures

In a prospective observational study, Dreyfuss *et al*[162] set out to determine the effect of sedation on therapeutic epidural steroid injections performed without LA. The authors found no difference in immediate postprocedure pain scores between those who received sedation with midazolam and/or fentanyl and those who did not. Approximately 25% of patients experienced >80% pain relief immediately following the epidural steroid injection despite the injectate containing no LA, and this did not differ between groups. This high rate was attributable to placebo effects in both groups.

Need for sedation

Kubulus *et al*[163] used a large database to retrospectively examine the influence of sedation on patient satisfaction for regional anesthetic injections. Unlike Cohen *et al*,[160] the authors found that sedation improved satisfaction with the procedure. Although this study has the strength of a very large sample size, it is limited by its retrospective nature and the confounding anxiety produced by the impending surgical procedure.

Table 7 Studies evaluating sedation during diagnostic or prognostic IA facet joint blocks and MBBs

Study	Design	Patients	Medications	Results	Comments
Manchikanti *et al*[159]	Randomized, double-blind, three-arm parallel group Measured pain relief before the block	60 patients with neck pain and LBP who were obtaining long-term relief with serial MBBs	From 1–5 mL of saline, midazolam (1 mg/mL) or fentanyl (50 µg/mL)	10% in the saline group, 20% in the midazolam group and 25% in the fentanyl group obtained ≥50% pain relief. For ≥80% pain relief, these proportions were 10%, 15% and 10%, respectively.	Light sedation used. No combinations of benzodiazepine and opioid were included; >40% had prior surgery. Did not measure the effect of sedation on block results. It is unlikely patients were blinded.
Manchikanti *et al*[158]	Randomized, double-blind, three-arm parallel group Measured pain relief before the block	360 patients with neck pain and LBP who were obtaining long-term relief with serial MBBs	From 1–5 mL of saline, midazolam (1 mg/mL) or fentanyl (50 µg/mL)	13%–15% in the saline group, 15%–20% of the midazolam group and 18%–30% of the fentanyl group had a placebo response (≥80% back pain relief) to diagnostic MBBs. A nocebo (worse pain) effect was observed in 5%–8% of the saline group, 8% of the midazolam group and 3%–8% of the fentanyl group.	Light sedation used. No combinations of benzodiazepine and opioid were included. Did not measure the effect of sedation on block results. It is unlikely patients were blinded. Re-analysis of patients from two earlier studies.
Manchikanti *et al*[156]	Randomized, double-blind, three-arm parallel group Measured pain relief before the block	180 patients with LBP who were obtaining long-term relief with serial MBBs	From 1–5 mL of saline, midazolam (1 mg/mL) or fentanyl (50 µg/mL)	7% in the saline group, 5% in the midazolam group and 13% in the fentanyl group obtained ≥50% pain relief. For ≥80% pain relief, these proportions were 2%, 5% and 7%, respectively.	Light sedation used. No combinations of benzodiazepine and opioid were included. Did not measure the effect of sedation on block results. It is unlikely patients were blinded.
Manchikanti *et al*[157]	Randomized, double-blind, three-arm parallel group Measured pain relief before the block	180 patients with neck pain who were obtaining long-term relief with serial MBBs	From 1–5 mL of saline, midazolam (1 mg/mL) or fentanyl (50 µg/mL)	8% in the saline group, 13% in the midazolam group and 27% in the fentanyl group obtained ≥50% pain relief. For ≥80% pain relief, these proportions were 5%, 8% and 8%, respectively.	Light sedation used. No combinations of benzodiazepine and opioid were included. Did not measure the effect of sedation on block results. It is unlikely patients were blinded.
Cohen *et al*[160]	Randomized crossover study	73 patients with suspected sacroiliac joint pain or complex regional pain syndrome received sacroiliac joint or sympathetic blocks with or without sedation	Midazolam and fentanyl, titrated to effect	In the primary crossover analysis, procedures done with sedation had a higher probability of a positive diagnostic block using ≥50% (OR 2.2; 95% CI 1.07 to 4.46; p=0.031) or ≥80% (OR 3.0; 95% CI 1.32 to 6.98; p=0.009) pain relief as the cut-off.	Light sedation used. A similar increase in the positive rate of the diagnostic block was noted for the parallel and omnibus (all sedation vs all no sedation) analyses. Sedation decreased procedure-related pain but did not affect satisfaction scores or 1 month outcomes.
Dreyfuss *et al*[162]	Prospective, observational	102 patients with cervical, thoracic or lumbosacral radiculopathy receiving epidural steroid injections	Midazolam and fentanyl, titrated to effect	In the sedation group, 49% reported ≥50% immediate relief of axial pain and 41% reported ≥50% relief of limb pain. In the no-sedation group, the corresponding proportions were 43% and 37%.	Light sedation employed based on patient preference. Epidural steroid injections are not a diagnostic procedure.
Kubulus *et al*[163]	Retrospective, observational	42 654 receiving neuraxial and peripheral nerve blocks for surgery	Opioids and benzodiazepines	Improved patient satisfaction in sedated patients	Sedation with opioids and benzodiazepines improved patient satisfaction with the procedure. The regional anesthetic blocks were performed in patients with and without preblock pain and were not diagnostic procedures. Patients were not blinded.
Cucuzzella *et al*[152]	Survey study	500 patients who received an epidural steroid injection or facet block	Diazepam, 2–5 mg intravenous	17% requested sedation before initial injection, with 28% stating they would request sedation before a second procedure.	Sedated patients reported slightly higher pain ratings. Factors associated with requesting sedation for a second injection included depression, anxiety and greater pain during initial injection.
Kim *et al*[153]	Prospective, observational	301 patients who underwent an epidural steroid injection or facet block	Oral sedation: diazepam 5–10 mg intravenous sedation: diazepam 5 mg	58% of patients requested sedation, with 96% of these choosing intravenous administration.	Request for sedation associated with greater anxiety. Among those who did not request sedation, 93% were satisfied with their decision while 1.5% wished they had received sedation; 90% of patients who received sedation stated their anxiety was controlled.

IA, intra-articular; LBP, low back pain; MBB, medial branch block.

Two studies performed in the same private practice setting found different results on the need for sedation before epidural steroid injections or facet blocks.[152 153] In a survey study by Cucuzzella *et al*,[152] 17% of patients requested intravenous sedation with diazepam before their initial procedure, with 28% reporting that they would request it before repeating the procedure. A history of anxiety, depression and higher pain during the initial procedure was associated with a patient requesting

sedation for anticipated follow-up injections. In a prospective follow-up study in which patients were offered oral or intravenous sedation with diazepam, 58% requested sedation, with 90% of these individuals being satisfied with the anxiolytic effect. Among those who did not request sedation, 93% were satisfied with their decision.[153]

Guidelines

Neither the American Society of Anesthesiologists[164] nor the SIS[165] recommend routine sedation for facet blocks, with scenarios that might warrant sedation including the need to lie still for prolonged periods of time (eg, a bilateral procedure in a patient with obesity with altered anatomy, difficulty lying prone secondary to pain) and debilitating anxiety. In contrast, 2009 guidelines by the ASIPP[166] that predated the randomized crossover study by Cohen *et al*[160] (ie, they considered only the earlier studies by Manchikanti *et al*) found sedation with midazolam or fentanyl had minimal effect on the evaluation of cervical and lumbar facet joint pain when stringent cut-off values were used.

Recommendations

Overall, we conclude that sedation should not be routinely administered for diagnostic or prognostic facet injections in the absence of reasonable indications. When sedation is used, patients should be educated on the increased risk of a false-positive block, and the lowest doses of short-acting sedatives, ideally without opioids, should be given; grade B evidence, low-to-moderate level of certainty.

QUESTION 8: WHAT IS THE IDEAL VOLUME FOR PROGNOSTIC FACET INJECTIONS?

Factors affecting injectate spread and rationale for considering injectate volume

The spread of fluid after injection into an anatomical space can theoretically be affected by several parameters including fluid viscosity, injection velocity, direction of the bevel tip and fluid volume, which may interact with one another. Studies performed for both MBB and epidural injections have found that injection velocity does not affect the degree of cephalad spread, while those evaluating the effect of bevel direction have been mixed.[167–169] Regarding composition, the viscosity of different LAs is roughly equivalent, but is less than that of contrast, which may underestimate spread (ie, higher viscosity is associated with less spread).[170]

Not surprisingly, the factor that most affects the degree of injectate spread, and therefore specificity, is volume. For procedures such as selective nerve root blocks and SI joint injections, lower volumes have been shown to enhance specificity.[171] Assuming appropriate needle position, the volume of the injectate is the most modifiable and predictable factor affecting injectate distribution. As noted in other sections, the validity and reliability of facet interventions is contingent on precision injections.[99] Injectate spread to structures other than the medial branch nerve or within the facet joint capsule, including the surrounding musculature, ligaments, intermediate/lateral branches, spinal nerve and epidural space, can undermine the specificity and positive predictive value of RFA.

Extrapolation from non-facetogenic clinical studies

There are no studies evaluating the effect of prognostic block volume on lumbar facet RFA, but several studies support the use of lower block volumes. In a large retrospective study examining predictive factors for pulsed RF of the occipital nerves, lower block volumes were associated with higher pulsed RF success rates.[172] A higher success rate was also found in patients who received a lower prognostic block volume in a study examining prognostic factors for celiac plexus neurolysis in patients with cancer pain.[161]

Medial branch blocks

In RCTs examining the efficacy of RFA of the lumbar medial branches, the volumes used for prognostic MBBs have varied to include 0.3 mL,[83] 0.5 mL,[18] 0.75 mL[81] and 1.0 mL,[82] with no detectable differences in outcomes stratified by injectate volume. For clinical trials evaluating therapeutic MBB, the volumes range between 0.5 mL[18 173–175] and 2 mL.[138 139] In a two-part study assessing the effect of the target point on 120 lumbar MBBs performed in 15 volunteers, Dreyfuss *et al*[99] found that a fluoroscopically guided 0.5 mL injection of contrast dye at the base of the superior articular processes of L2 through L5 resulted in spread to the neural foramen or epidural space in 16% of cases, and diffused into the posterior back muscles 100% of the time. When it occurred, the degree of epidural spread was believed to be clinically insignificant based on assessment with postinjection CT scanning. Aberrant spread was reduced when a more caudad location midway between the upper border of the transverse process and the mamillo-accessory ligament was targeted, rather than at the superomedial border of the transverse process. The authors also found that the medial branch was bathed during all nerve blocks and concluded that a smaller volume would be sufficient.

In a small (n=6) cadaveric study that sought to assess optimal MBB volumes, Wahezi *et al*[176] found that both 0.25 and 0.5 mL of contrast bathed the targeted nerves (n=18) in all injections, but that using lower volumes significantly reduced aberrant spread to adjacent structures, specifically more superficial muscles and distal segments of the dorsal rami. They concluded that the lower volume was more specific and should ideally be used for prognostic blocks before medial branch RFA.[176]

In a randomized study performed in 24 patients by Cohen *et al*[98] in the cervical spine, injection of 0.25 mL was found to bathe the target nerve at approximately the same (93%) rate as a 0.5 mL injection, although with a lower rate of aberrant spread. Paradoxically, more people who received blocks with 0.25 mL obtained ≥50% relief (50% vs 25%), although the difference was not statistically significant. The most common pattern of aberrant spread was to an adjacent, non-targeted spinal level, which occurred in 57% of cases at C3. Whereas this is the only clinical trial evaluating MBB outcome differences between injectate volumes, anatomical differences between the lumbar and cervical spine regions warrant caution with generalization.

Intra-articular facet joint injections

The facet joint is a true synovial joint with a capsule that has a reported capacity of 1.0–2.0 mL of fluid.[177] Yet in RCTs examining the efficacy and prognostic value of lumbar facet IA injections, a wide range of volumes have been used including 0.25–0.50 mL,[84] 0.3 mL,[178] 0.5 mL,[18] 0.7 mL,[61] 1.0 mL,[179 180] 1.5 mL,[53 138 139] 3.0 mL[66] and 8.0 mL.[41] Whereas high volumes may result in rupture of the joint capsule and inadvertent spread to other potential pain generators, thereby undermining specificity, using an insufficient volume may conversely fail to anesthetize the joint, resulting in a false-negative block. Considering the high failure rate of IA blocks and poor long-term efficacy,[14 18 100] it is not surprising that there is little correlation between IA block volume and pain relief.

In a study involving 70 IA injections performed in 30 patients, most of whom had osteoarthritis, Dory[181] found that rupture of the facet joint capsule was very common, occurring with between 1.0 and 3.0 mL of injectate. In another study, capsule rupture and extravasation into the epidural space occurred when volumes exceeding 1.5 mL were injected into the joint.[182] When capsular rupture did not occur, only 17% of the patients had pain relief, leading the authors to conclude that high volume injections overestimate the prevalence of lumbar facet joint pain. When leakage occurs laterally, branches of the dorsal ramus can be anesthetized. If the capsule is ruptured or leakage occurs medially, the injectate often spreads into the epidural space and/or intervertebral foramen, which can lead to false-positive results.[181 182] Theoretically, capsular disruption can also lead to worsening pain and stiffness.

Recommendations

Lumbar MBBs should be performed with ≤0.5 mL (total volume) to reduce spread to adjacent structures; grade C recommendation, low level of certainty. Lumbar IA facet joint injections should be performed with a volume of <1.5 mL to prevent capsular rupture and reduce spread to adjacent structures; grade C recommendation, low level of certainty.

QUESTION 9: ARE INTRA-ARTICULAR FACET OR MEDIAL BRANCH BLOCKS WITH STEROIDS THERAPEUTIC?

Rationale for corticosteroids

The use of IA corticosteroid injections for facet joint pain is controversial and predicated on the belief that an inflammatory component that may respond to local steroids is responsible for a predominance of symptoms. For MBB, the theoretical foundation is weaker, and is based on the observation that the medial branches may be trapped beneath the mamillo-accessory ligament, which is most common at L5 (20%) but may also occur at higher levels.[183 184] This entrapment neuropathy has been implicated as a source of LBP.[183]

Randomized controlled trials evaluating intra-articular steroids

In a large randomized study involving 109 patients, no difference was found between large-volume (8 mL) IA saline injections, IA corticosteroid and LA, and the same mixture injected around two facet joints.[41] Two studies published in the *New England Journal of Medicine* that prescreened patients who responded to previous diagnostic IA lumbar facet injections and cervical MBB also failed to demonstrate benefit for lumbar and cervical IA facet joint injections, respectively.[180 185] In the randomized controlled study performed in 101 patients with lumbar facet joint pain, only small, non-significant differences between the injection of saline and depo-corticosteroid were observed throughout the study, with 22% in the steroid group and 5% in the placebo group obtaining meaningful benefit at 6 months.[180] In the smaller of the two studies performed in 41 individuals with whiplash injury, Barnsley *et al*[185] found no significant differences between cervical IA bupivacaine and depo-steroid, with the median time to return of pain to 50% of baseline being 3 days in the steroid group and 3.5 days in the control group. Kennedy *et al*[186] performed a small double-blind study comparing the effect of lumbar facet IA steroids versus saline on the need for RFA in 24 patients prescreened with MBB. The authors found no difference in either the need for denervation or the time that elapsed before the denervation between treatment groups. In stage 1 of a two-stage randomized, double-blind trial, Cohen *et al* found no significant differences for pain relief or functional outcome between lumbar facet IA injections with steroid and bupivacaine, MBB with steroid and bupivacaine or saline control MBB for up to 6 months postinjection.[18]

Although these studies provide evidence against the use of IA steroids, a small randomized, double-blind study by Ackerman and Ahmad[61] suggests that individuals with acute, inflammatory pain may benefit from IA steroids. Among 46 patients with clinical symptoms consistent with acute lumbar facet joint pain (mean age 39.3 years, median duration 7.6 weeks) and positive SPECT scans, 61% who received IA facet LA and steroid injections obtained ≥50% relief 12 weeks post-treatment vs 26% of those who received therapeutic MBB. Observational studies also suggest intermediate-term relief in individuals with positive SPECT.[53 66 117] Two older randomized studies compared MBB with IA injections containing LA and steroid in patients who were not prescreened with facet blocks, finding little difference between groups.[138 139] Marks *et al*[138] found only marginally longer relief with IA steroids in 86 patients with axial LBP, with only 7 patients in the IA group and 6 in the MBB group reporting persistent relief at 3 months. In an earlier study by Nash[139] (n=67), the authors reported that comparable numbers of patients obtained significant relief at 1 month after MBB and IA injections with steroid and LA. In a more recent double-blind randomized study comparing IA and intramuscular steroids in patients with axial LBP who were not prescreened for facetogenic pain (n=60), Ribeiro *et al*[187] found that IA steroids were slightly better than intramuscular steroids on some, but not most, outcomes through 6-month follow-up. These studies demonstrating a lack of evidence for IA facet injections in patients with chronic LBP are consistent with evidence-based guidelines,[16 21] which recommend against the injections. One caveat with placebo-controlled trials that is not commonly appreciated is that the IA injection of saline or LA may itself provide prolonged therapeutic benefit.[188]

Randomized controlled trials evaluating MBB

Dias da Rocha *et al*[173] performed a non-randomized placebo-controlled study in 104 individuals with suspected facet joint pain, injecting saline around the medial branches followed by lidocaine injection in those who failed to benefit after 10 min. The authors found that 16.3% (n=17) of individuals responded to placebo, while 31.7% (n=33) failed to obtain at least 50% relief from lidocaine. Among the 54 lidocaine responders, two-thirds maintained pain relief at 3 months. In phase I of a three-arm double-blind study that compared IA LA and steroid lumbar facet injections, MBB with LA and steroid, and saline control blocks, Cohen *et al*[18] found no significant differences in any outcome measure at any time point in the 6-month follow-up (1 month success rates of 12%, 11% and 6%, respectively, which declined at subsequent visits). In a systematic review that evaluated two trials by the same group of investigators that included a total of 204 patients treated with serial lumbar MBB with lidocaine, lidocaine and steroid, lidocaine and Sarapin, or lidocaine, steroid and Sarapin, the authors found strong evidence for benefit which lasted over 6 months in most people.[189] One of these randomized studies evaluating patients who received MBB with LA or LA and steroid for 2 years found that patients received significant relief (≥50% reduction in pain score) and functional improvement for between 82 and 84 weeks out of 104 weeks, requiring approximately five to six treatments, with each treatment producing an average 19 weeks duration of relief.[174] Flaws in these studies include the high proportions of

patients taking opioids and having had previous back surgery, and the lack of control groups and absence of blinding.

Unique issues for steroid injections

Although one study supports the use of IA facet joint steroid injections in individuals with acute pain, this study was small, did not prescreen patients with diagnostic blocks and used SPECT scans to identify candidates, which is expensive and exposes patients to a substantial amount of radiation.[61] There is also a high failure rate associated with IA facet injections, which ranges between 29% and 38% per joint, and 46% and 64% per patient (ie, percentage of patients in whom there was at least one failed injection).[18 100] In two studies that examined the correlation between IA spread and outcomes, only the uncontrolled study showed a higher success rate with successful arthrography.[100] In the subset of individuals who do respond to facet injections, there is some evidence that repeat injections are associated with poorer treatment response,[40] and may be associated with long-term consequences such as immunosuppression, increased diabetes risk and osteoporosis.[190–192]

Recommendations

We recommend against the routine use of therapeutic facet injections, although we acknowledge that in patients who may be at risk of adverse consequences from RFA (eg, young athletes, older individuals on anticoagulation therapy or with implantable cardiac devices) or in whom there is a strong likelihood of success (eg, individuals who obtained prolonged relief from previous diagnostic injections with or without steroids), it may reasonable to add steroids to a block in the hope of deriving intermediate-term relief; grade D, moderate level of certainty.

QUESTION 10: WHAT SHOULD THE CUT-OFF BE (IE, PER CENT RELIEF) FOR DESIGNATING A BLOCK AS 'POSITIVE', AND IS THERE ANY BENEFIT IN USING NON-PAIN SCORE OUTCOME MEASURES?

Guidelines

Numerous studies have been devoted to determining the optimal cut-off for proceeding to RFA. The SIS guidelines on lumbar facet denervation specify that complete relief in a distinct topographical area is necessary for a particular block to be positive (though some pain may persist from other sources),[16] while the ASIPP guidelines note that there is stronger evidence for a cut-off of 75% than 50%. Both guidelines recommend that these cut-offs be used for dual blocks. Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines propose that a 30% or greater reduction in pain be considered a moderately clinically important improvement and that reductions of 50% or greater can be considered a substantial improvement.[193] Although this cut-off was intended to categorize the response to pain treatments, given the implicit (although imperfect) correlation between the block and definitive treatment, in certain circumstances these cut-offs may also provide a benchmark for prognostic information despite not being validated in this context (personal communications from Robert Dworkin, Robert Kerns and Srinivasa Raja). High cut-offs may also be difficult to achieve physiologically given that facet degeneration almost never occurs in isolation. For example, radiological studies indicate that disc degeneration almost always precedes and is greater in magnitude than facet degeneration, and that muscle pathology accompanies facet joint inflammation.[194–196]

Factors that can affect pain relief

Whereas it may appear to be axiomatic or self-evident that higher cut-off values should translate into higher success rates (ie, individuals in whom facetogenic pain represents a greater contribution to their back pain burden than other sources should do better), it is difficult or impossible to tease out the proportion of pain relief due to the block itself and factors such as inadvertent spread of LA to other pain-generating structures, the effect of superficial anesthesia on myofascial pain, sedation and the placebo response, which is generally higher than the intrinsic effect of therapies for chronic pain.[14 99 132 197]

Studies comparing different pain relief cut-offs

Most randomized studies evaluating lumbar facet RFA have used ≥50% pain relief from a prognostic block as an inclusion criterion,[7 17–19 69 83 84 198] and several studies have compared prognostic block cut-off values of 50%–70% or 80% for lumbar facet and other denervation procedures[6–8 68 69 135 172 199–201] (see table 8 for study details). The first study to examine this question was a retrospective study in 262 patients that found no difference in 6-month lumbar facet RFA outcomes between individuals who experienced at least 50% but <80% vs ≥80% relief with MBB.[199] A similar study that sought to examine the effect of MRI findings on lumbar facet RF outcomes found identical success rates in a high index group that obtained ≥80% relief after two MBBs and those who had either one block done or obtained ≥80% pain on only one of two blocks.[68] A recent study by Holz and Sehgal[135] found no correlation between the percent pain relief after either the first or second MBB and lumbar and cervical RFA outcomes at 3 months. In the only prospective study (n=61) to examine the effect of lumbar MBB pain relief on RFA outcomes, Cohen *et al*[6] found no difference in 10% incremental cut-offs between 50% and 100% relief, with patients who obtained <50% relief with their diagnostic block faring worse. Of note, the predesignated cut-off for a successful RFA outcome was 50% so that some patients who experienced < 50% pain relief on their MBB but felt subjective improvement and proceeded to RFA, experienced similar improvement after RFA but were considered treatment failures. Several other studies examining differences in diagnostic block cut-off points and RF outcomes for cervical facet joint pain, SI joint pain and occipital neuralgia also found no benefit for using threshold values above 50%.[69 172 200]

Not all studies have reported comparable relief with lower cut-offs. A retrospective study by Manchikanti *et al*[201] found that for up to 2 years, individuals who experienced ≥50% pain relief but <80% relief with one or two blocks had poorer outcomes than those who experienced at least 80% relief (89.5% vs 51%). At 1-year follow-up, the reported success rates in the ≥50% and ≥80% relief groups were 75% and 93%, respectively, indicating that three-fourth of the people who would have been denied treatment because of implementation of the higher cut-off threshold actually benefitted. The main shortcoming of this study is that not all patients underwent RFA (number not provided). In another retrospective study, Derby *et al*[8] found a higher proportion of patients who obtained ≥80% relief with single and double diagnostic blocks experienced over 50% relief after RFA compared with those who obtained between 50% and 80%, although a direct statistical analysis was not performed. In the group with ≥80% relief, 84% experienced a positive RFA outcome, defined as ≥50% pain relief, vs 56% who obtained ≥50% but <80% relief on their diagnostic blocks.

Non-pain relief measures of benefit

Whereas pain relief (eg, mean reduction in average pain) is by far the most common primary outcome measure in interventional and analgesic pain trials, two studies evaluating epidural

Table 8 Studies comparing facet joint radiofrequency ablation outcomes based on per cent relief with diagnostic blocks

Study	Design	Number of patients	Results	Comments
Cohen *et al*[6]	Prospective	61	54% success rate, with no difference in categorical outcomes or correlation in 10 percentage point increments. Only one in six people who underwent RFA after obtaining <50% relief on MBB had positive outcome.	Cut-offs at 10% increments from 50% to 100% relief. Poorer outcomes in six individuals who had <50% relief with single block; ≥50% pain relief 6 months after RFA designated as positive response.
Cohen *et al*[199]	Retrospective	262	52% success rate in ≥50% cut-off group vs 56% in ≥80% group.	Multicenter study evaluating single blocks.
Holz and Sehgal,[135]	Retrospective	50	53.1% relief in individuals with ≥70% relief on both MBB vs 44.4% relief in those with ≥70% relief on only one of twio MBB.	Included both lumbar and cervical facet RFA. Sixty patients lost to follow-up. Greatest pain relief in patients with >8 hours of pain relief after lidocaine blocks.
Cohen *et al*[69]	Retrospective	92	56% success rate in ≥50% cut-off group vs 58% in ≥80% group.	Evaluated cervical facet RFA. Multicenter study evaluating single blocks.
Stojanovic *et al*[68]	Retrospective	77	47% success rates in both high index group who obtained ≥80% pain relief on two blocks and those who received one block, or had ≥80% relief on only one of two blocks.	Seventeen people in 'high index' group.
Cohen *et al*[134]	Retrospective, case-control	511	74% pain relief from diagnostic facet blocks in individuals with a positive RF outcome vs 72% in those with a negative outcome.	Multicenter study designed to determine whether IA or MBB are superior as prognostic tests.
Derby *et al*[8]	Retrospective	51	Success in 22% (2/9) of patients with ≥50% but <70% relief vs 79% (33/42) in those with ≥70% relief.	≥50% relief designated as success. Patients had both single and double blocks.
Manchikanti *et al*[201]	Retrospective	110 to 152 in control comparison group	At 1-year follow-up, 93% in 80% cut-off group had a positive outcome vs 73% in the 50% cut-off group. At 2 years, success rates were 89.5% and 51%, respectively.	Compared double block outcomes with their own historical controls. Patients treated with both 'therapeutic' MBB and RFA (breakdown not provided). Since MBB have not been shown to provide long-term benefit, validity is questionable.
McCormick *et al*[205]	Prospective	55, 28 who had 2 blocks and 27 who had a single block	In the single block group, 43% and 46% had ≥50% improvement in pain and function vs 59% and 63% in those who had two blocks.	Those who had 50%–74% relief on the initial block underwent a confirmatory block, while those who obtained ≥75% relief proceeded to RFA.
Derby *et al*[206]	Retrospective	182	Single block group: ≥50 <80% relief 50% RFA success rate; ≥80% relief: 72% RFA success rate. Double block group: ≥50 <80% relief: 85% RFA success rate; ≥80% relief: 100% success rate (13/13).	Unclear why some patients underwent single vs double blocks. Excluded some patients with suspected multiple sources of pain.

IA, intra-articular; MBB, medial branch block; n, number; RFA, radiofrequency ablation.

steroid injections published in the *New England Journal of Medicine* used LBP functional capacity as the primary outcome measure.[202 203] In individuals with chronic pain, improving function may be a more realistic benchmark than pain relief, and both the Roland-Morris Disability Questionnaire and ODI are meant to provide a cross-sectional measure of function. However, in practice the parameters assessed in these instruments (sitting and standing tolerance, walking distance, ability to travel, dressing, lifting, sex, sleep, etc) preclude their use over the brief 2–4-hour therapeutic window after facet blocks. The same holds true for medication reduction, as long-acting medications cannot be tapered over a period of 3 hours, and withholding opioids may elicit hyperalgesia. In the prospective study by Cohen *et al*[6] evaluating the effect percent pain relief on prognostic blocks has on RFA outcomes, when the six patients with <50% pain relief on their diagnostic block underwent RFA based on their subjectively reported functional improvement and satisfaction, only one experienced a positive 6-month categorical outcome, which was defined as ≥50% relief.

Since patient recall is subject to error and expectation bias, the most objective means to measure benefit is by the use of 'real-time' pain diaries. But pain relief must be assessed in the context of analgesic consumption and function, so that the use of pain diaries to assess response after prognostic injections should evaluate function as well as analgesic requirements. In accordance with the US Food and Drug Administration (FDA) guidelines on identifying responders,[204] a clinically significant need for increased analgesic consumption for the index condition (ie, LBP) after a block would preclude that block from being designated 'positive'. For the same reasons, a modest reduction in pain that is attributed to a decrease in activity levels should be considered evidence against proceeding to RFA. Because the limitations in using non-pain-related measures as the benchmark for designating a prognostic block as positive are related to the relatively short duration of action of LAs, should sustained-release or ultra-long-acting formulations of LA become standard of care, the use of objective measures of function (eg, use of a pedometer, medication reduction, functional capacity) to assess block success will become an area ripe for investigation.

Predictive modeling

As noted elsewhere, clinical prediction tools might someday be used to achieve personalized medicine. In this scenario, the amount of pain relief from a block might be used as part of an algorithm to select patients for RFA. For instance, in a young athlete with subacute back pain and an equivocal presentation, 50% pain relief on an initial block might warrant a confirmatory block, while the same person who obtains 75% relief might benefit from proceeding to RFA. This model is supported by preliminary evidence. A clinical study by McCormick *et al*[205] used the amount of pain relief on an initial block to decide whether a second block was warranted (ie, those with 50%–74% relief), finding no difference in outcomes between those who had single versus double blocks. In a retrospective analysis by Derby *et al*,[206] the authors reported a 50% RFA success rate in 100 patients who underwent a single block that afforded between 50% and 79% relief versus a 72% success rate in those who obtained ≥80% relief from a single block. However, among 33 patients who obtained between 50% and 79% pain relief following two MBBs, the success rate was 85%.

Recommendation

In summary, this committee recommends that a ≥50% reduction in pain be considered a positive block, although we recognize

that studies should be performed to determine whether lower cut-offs may prove to be optimal. Although there are studies showing that patients with ≥80% relief are more likely to have a positive response to RFA than those with less relief, a significant proportion of patients who achieve a threshold of 50% but <70% or 80% relief will benefit from RFA. In the absence of any reliable treatment options for patients who obtain ≥50% but <80% relief, the committee opts to maximize access to care in a clinical context. Secondary outcomes such as medication usage, activities during the duration of the block, and satisfaction may be considered when deciding whether or not to proceed with RFA (ie, a 50% reduction in pain that is attributed to decreased activity, residual sedation or an increase in analgesic consumption should not be considered a positive block). It is also possible that future clinical prediction modeling will result in different cut-off values for different clinical scenarios; grade B recommendation, moderate level of certainty.

QUESTION 11: HOW MANY PROGNOSTIC BLOCKS SHOULD ONE PERFORM BEFORE RADIOFREQUENCY ABLATION?

Basis for multiple blocks and false-positive rate

The number of blocks that should be performed before lumbar medial branch RFA is a subject of great controversy. In the only guidelines espoused by pain organizations, SIS and the ASIPP both advocate two blocks before RFA, with the latter concluding that the evidence for diagnostic accuracy is poor (<75% relief) to limited (≥75% relief) when single blocks are used.[1 16] The rationale for performing either placebo-controlled blocks, or 'blinded' comparative LA blocks, in which two LAs with different durations of action are used for blocks on two separate occasions, and longer relief from the longer-acting agent is necessary for diagnosis, is that it reduces the placebo effect. However, the placebo effect is only one of several causes of false-positive blocks, which include leakage of the injectate into adjacent pain-generating structures such as muscles and the epidural space; excessive use of superficial anesthesia; the use of sedation and not participating in one's normal activities after the injection.[14 99 132]

The false-positive rate for IA injections and MBB is estimated at between 17% and 41%, and may be higher for individuals with previous surgery and psychopathology.[50 117 133 207 208] However, most of these studies have calculated the false-positive rate based on comparative LA blocks, which suffer from low sensitivity (<60%).[209] In the absence of any reference standard for diagnosis, estimates of sensitivity and specificity are always speculative, with few studies having examined the false-positive rate based on placebo-controlled blocks (table 9). In these studies, which examined both MBB and IA injections, the false-positive rate varies from 16% to upward of 30%.[18 45 146 210]

There are certain contexts in which a screening test with high specificity and positive predictive value is warranted. These include when the definitive treatment is associated with high risks and/or costs (eg, multilevel spine fusion). Such tests can also be warranted in conditions that have relatively low prevalence. This is due to the fact that the diagnostic confidence of a test is predicated on the sensitivity and specificity, and on disease prevalence (ie, pretest probability). Specifically, since isolated facet-mediated pain may have a lower prevalence in certain patient populations than the reported false-positive rate of a single MBB (eg, very young, sedentary people), some have advocated for a more rigorous diagnostic criterion such as dual MBB.

Conversely, others argue that the relative risks of RFA are less than those of alternative treatments (eg, surgery, opioids) in people who have already failed conventional therapies. In this setting, a prognostic block associated with high sensitivity and negative predictive value is desired. Otherwise, individuals with a false-negative injection may be denied treatment, referred for surgery or started on expensive and less effective treatments such as chronic opioid therapy.

False-negative blocks

There are several reasons for false-negative blocks, including failure to envelop the target nerve (infrequent since 0.5 mL of LA spreads to an area >6 cm^2), intravenous uptake (incidence range 4%–19%, with digital subtraction being the reference standard for detection), inability to access the joint for IA injections (incidence 29%–38%), aberrant, non-medial branch innervation (approximately 11%), excessive procedure-related pain including muscle pain and spasm, failure to adequately assess pain relief, comorbid spinal conditions and opioid-hyperalgesia from abrupt cessation of opioids, among others.[14 100 106 127 143 211]

Table 9 Randomized studies evaluating a placebo response rate using saline control injections

Study	Number of patients	Study design	Type of blocks (placebo arm)	Placebo response or false-positive rate*	Comments
Revel *et al*[45]	80–38 who received placebo	Randomized, parallel group	IA with 1 mL saline	18% placebo response	Response defined as ≥75% relief.
Cohen *et al*[18]	229–47 who received placebo	Randomized, three-arm parallel group	MBB with 0.5 mL saline	30% placebo response	Response defined as ≥50% relief.
Lord *et al*[209]	50 patients with whiplash	Randomized, three-period crossover	Cervical MBB with 0.5 mL bupivacaine, lidocaine and saline	40% placebo response, false-positive rate (concordant relief with LA blocks but positive response to placebo) 19%	Response defined as longer pain relief (complete or profound) with bupivacaine than lidocaine, and a negative response to saline. False-negative rate (positive but discordant response to LA injections but negative response to placebo) 32%. Sensitivity 54%, specificity 88%.
Dias da Rocha *et al*[173]	104	Patient-blinded, one-way crossover	Lumbar MBB with 0.5 mL saline, and if negative, lidocaine	16% placebo response	Response defined as ≥50% relief. All patients received saline and if negative, lidocaine MBB after 10 min.
Schütz *et al*[146]	60	Single-blind, three-way crossover	Bilateral lumbar IA injections with 1.5 mL of mepivacaine (verum), saline (placebo) or extra-articular needle placement without injection (sham)	Sham and placebo groups had 20% and 38% response rates, respectively, at 1 hour	Response defined as >2-point decrease in back pain. Non-inferiority shown between placebo and verum injection.

Injections in lumbar spine unless specified.
*False-positive rate based on positive response to verum and negative response to sham injection.
IA, intra-articular; LA, local anesthetic; MBB, medial branch block.

Several studies have sought to determine the incidence of false-negative blocks, via repeat blocks and RFA response to negative MBB responders. In a retrospective chart review by Derby *et al*[9] using ≥70% pain relief as the criterion for a positive response, the estimated false-negative rate was 46.7% in individuals who obtained <50% relief following an initial block, 47.1% in those with 50%–69% relief and <10% in those with ≥70% relief. In those who underwent RFA, 100% (four of four) of those who had <50% relief on their first block, and 50% (two of four) who had between 50% and 69% relief had a positive outcome. When attempting to identify a subset of patients prone to false-negative blocks, the authors found that individuals with 'delayed' (ie, discordant) relief based on the expected duration of action of the LA were most likely to respond to RFA among those with negative blocks (three of four, 75%). The investigators reported sensitivity, specificity, positive predictive and negative predictive rates of 55%, 77%, 78% and 53%, respectively. These results, along with the low reported sensitivity and negative predictive values, indicate that comparative LA blocks will result in a substantial proportion of patients who would otherwise be denied a beneficial treatment. The results are consistent with another retrospective analysis by Holz and Sehgal[135] that found no significant difference in pain relief or function following lumbar or cervical RFA between patients who obtained longer pain relief (≥70%) with bupivacaine than lidocaine, and those with discordant responses to comparative LA MBB (53.1% vs 44.4%).

Indirect comparison of studies using different numbers of blocks

The two randomized, controlled studies evaluating facet joint RFA (including one in the cervical spine) that used multiple blocks, both yielded positive findings,[82 212] while those that employed single blocks have yielded mixed results.[17 19 81 83–85 213] However, there were numerous other differences between these studies and other publications. In the study (n=24) by Lord *et al*[212] evaluating cervical medial branch RFA, the authors performed three screening blocks with lidocaine, bupivacaine and saline, requiring concordant relief with lidocaine and bupivacaine and no benefit with placebo. They defined a positive block as complete alleviation of pain, and created four to six lesions per level. In the study by Nath *et al* (n=40),[82] the authors required ≥80% pain relief from comparative LA blocks, and created six empirical lesions per level. This study group screened 376 patients to enroll 40 participants. A clinical audit by Dreyfuss *et al*[23] reported that 87% of patients experienced at least 60% pain relief 12 months following lumbar medial branch RFA. However, in addition to selecting patients with comparative LA blocks, investigators required at least 80% pain relief; screened all patients with imaging, electromyography to establish intact multifidi, and Beck Depression Inventory scores; used 16-gauge electrodes for denervation and confirmed the technical success of the procedure via confirmation of multifidus denervation. In contrast, the negative study by Leclaire *et al*[85] required 'significant relief' for at least 24 hours after IA lidocaine injections, which is a LA with an elimination half-life of <2 hours. This study also employed an ablation technique that resulted in small lesions that likely missed target nerves, and screened only 76 patients to obtain 70 study participants. Thus, excluding individuals with non-facetogenic sources of pain and maximizing the chance for a technically successful procedure appear to be critical components for a 'successful' study. Overall, studies that reported clear-cut or equivocally positive results[18 81 82 84] used more stringent selection criteria than those studies that reported unequivocally negative results (14% vs 34% enrollment rate among screened study candidates).[17 19 85]

Studies comparing different numbers of blocks

There has been only one randomized trial in the peer-reviewed literature comparing outcomes stratified by different prognostic block paradigms. Cohen *et al*[7] randomized 151 patients to receive either lumbar medial branch RFA based on clinical findings without prognostic blocks, RFA after a single positive MBB with bupivacaine (defined as ≥50% pain relief lasting at least 3 hours) and RFA only after positive comparative LA blocks with both lidocaine and bupivacaine performed in random order. In the group that received RFA without a block, 17 of 51 patients (33%) experienced a positive categorical outcome, which was designated as ≥50% reduction in average back pain at 3 months coupled with a positive global perceived effect. In the single block group, 16% of the 50 randomized patients achieved a positive categorical outcome (7 from RFA, 1 from prolonged effect from LA), while in the double-block group, 11 (22%) attained a positive outcome (9 from RFA). However, when only individuals who underwent RFA were considered, the success rates in the zero, one and double-block groups were 33%, 39% and 64%, respectively. When the authors calculated costs, the zero-block group had the lowest cost-per-effective procedure rate, and the lowest overall cumulative cost. The explanation behind these findings was that the zero-block group included all placebo responders and excluded no false-negative blocks, while the double-block group excluded most placebo responders and also some false-negatives (ie, true positives). This indicates that at the reported Medicare reimbursement rates, performing prognostic lumbar MBB will decrease the overall number of responders, and increase costs, with multiple blocks resulting in even lower numbers of responders and higher costs. Yet for scenarios where maximizing the positive predictive value MBB is desired, including studies designed to assess RFA efficacy and unproven facet arthrodesis procedures, multiple blocks could be indicated since they effectively screen out false-positives.

In a retrospective study, Stojanovic *et al*[68] designed to determine the association between imaging findings and RFA outcomes, the authors also examined the effects the number of blocks and the pain relief experienced had on treatment results. Among the 17 patients who obtained ≥80% pain relief from dual MBB, the 47% success rate was identical to those who had either one block, or obtained <80% pain relief from at least one of two blocks. In a larger (n=511) case-control study designed to determine the relative predictive value of MBB and IA blocks before lumbar medial branch RFA, Cohen *et al*[134] reported no significant differences in success rates based on numbers of blocks (63% in individuals who received one prognostic block vs 70% in those who received two or more). There was no difference in outcomes based on whether the blocks were both MBB, both IA blocks or combination blocks (IA followed by MBB), with only undergoing MBB being associated with a positive outcome. Derby *et al*[8] performed a retrospective study in 51 patients, 13 of whom underwent double MBBs, both with bupivacaine. The authors defined a positive block as ≥50% pain relief lasting at least 45 min postprocedure. Two-thirds of the patients were on opioids. The authors reported that 63.2% of single-block patients experienced a positive 3-month RFA outcome vs 84.6% in those who received double blocks.

For other conditions treated with RFA, the use of screening blocks is also of questionable utility. For example, van Eerd

et al[214] reported a 55% success rate when evaluating a new approach for cervical medial branch RFA without the use of a screening block. In a randomized study evaluating the utility of a single prognostic block before RFA for knee osteoarthritis in 54 individuals, McCormick *et al*[215] reported 6-month success rates of 64% in the no-block group and 59% in the single-block group. Yet, the lower relative prevalence rate of facetogenic pain in individuals with LBP compared with those with neck pain, and arthritis in those with knee pain, suggests there is a higher likelihood for false-positive diagnostic blocks in the lumbar spine compared with the cervical spine or knee.

Weighing false-positives versus false-negatives

There is evidence in the form of observational studies that the success rate for medial branch RFA will increase with the number of blocks, but this will inevitably occur at the expense of patients who are deprived of treatment. The proportion of the higher success rate that is attributable to a higher placebo response rate with multiple blocks is unclear; the only way to obviate this dilemma would be to perform placebo-controlled blocks, which are difficult to justify for a relatively safe procedure. Two observational studies illustrate the high success rates that can be achieved with stringent selection. As noted above, the prospective cohort study by Dreyfuss *et al*[23] reported that 87% of 15 patients who experienced at least 80% relief with dual-comparative LA MBB obtained at least 60% pain relief maintained at 1 year after RFA, with 60% obtaining at least 90% relief. However, along with double blocks, the authors screened 460 patients for the study, with 138 presenting for full physical examinations, suggesting a low prevalence of isolated facetogenic pain, a high false-negative rate or a combination of the two. In a more recent study using similar selection criteria and RF parameters, MacVicar *et al*[216] reported that 56% of 106 patients obtained complete pain relief and functional restoration lasting a median of 15 months. Whereas the authors were not able to determine the exact number of patients screened, they estimated it to be around 575. In a meta-analysis performed by Lee *et al*[217] evaluating five randomized controlled studies and 423 patients with 6-month follow-up data who underwent either lumbar medial branch RFA or a control procedure (sham or epidural steroid injection), the authors found a statistically and clinically significant 1.5-point difference in back pain scores favoring denervation. Notably, all studies in this review used either 1 or 0 (n=1) block, and one included patients with 'equivocal' relief. In a prospective, observational study, McCormick *et al*[205] performed double blocks in individuals who experienced between 50% and 75% relief (n=28), but proceeded to RFA following single blocks if the pain relief obtained was ≥75% (n=27), and found no significant differences in outcomes.

Clinical prediction tools

It is possible that in the future, predictive modeling programs based on large-scale registries or complex trial designs may find that different people require different RFA selection paradigms (personalized medicine). Proceeding straight to RFA without blocks is preferred in situations where costs and number of procedures are the primary concerns. Potential examples include an elderly person who is on anticoagulation therapy and presents with paraspinal tenderness, marked facet arthropathy on MRI and no psychopathology or those in whom blocks could pose significant risks or hardships (eg, a person with extreme needle phobia who might require sedation that could undermine the accuracy of a block, or a service member deployed at a forward operating base). Double MBBs provide an advantage and are preferred when maximizing the success rate of medial branch RFA is the primary concern. Examples include a person with minimal imaging pathology, an equivocal physical examination or multiple risk factors for treatment failure; a young athlete in whom denervating spinal muscles could affect performance and someone with spondylolisthesis or other risk factors for spinal instability in whom denervation could theoretically worsen their clinical condition.

Recommendation

The committee recommends a single block. We found moderate evidence that dual blocks result in a higher subsequent success rate for medial branch RF, but that the use of a zero-block paradigm results in the highest overall number of patients with a positive response to the RFA. This has led some, including this committee, to a clinical compromise of accepting the results of a single MBB for identifying denervation candidates, with some data suggesting that higher RF treatment response rates occur in those reporting a higher degree of relief with a single block. In an era of personalized medicine, the committee believes that known variables should be used to tailor care to the needs of the individual patient and to the goals of the practice environment; grade C recommendation, low-to-moderate level of certainty.

QUESTION 12: IS THERE EVIDENCE FOR LARGER LESIONS TO IMPROVE OUTCOME MEASURES FOR RADIOFREQUENCY ABLATION? IF SO, HOW CAN LESION SIZE BE INCREASED?

Rationale for lesion size for lumbar facet denervation

In order to effectively perform RFA of the medial branches and dorsal rami innervating the lumbar facet joints, it critically important that physicians understand the electrophysiological principles, technical and anatomic aspects of RFA.[14 218–220] Procedural challenges exist for lumbar RFA based on the need to balance limiting the size of thermal lesions to avoid lesioning non-targeted tissues and enhancing lesion size to increase the likelihood of capturing the targeted small-diameter nerve fibers. The diameter of lumbar medial branches is <2 mm and the L5 dorsal ramus transverse diameter has been measured at 0.5 mm.[221 222]

The main rationale for expanding lesion size is to increase the maximal tolerable margin of error for coagulating the targeted medial branch or dorsal rami, which can vary in location and in the number of branches that innervate the facet joint.[223] The margin of error is the maximum distance that an RF cannula can be placed from a targeted structure and still create a lesion that envelops the structure.[224] With limited-sized lesions and small diameter nerves, the tolerable margin of error is small.

It is important to emphasize that whereas patient selection is the most effective way to improve RFA success rate, because withholding treatment from individuals who are at high risk for failure but could greatly benefit from ablation may severely curtail access (ie, high-risk, high reward category such as those on opioids or who are unable to work because of back pain), decreasing the technical failure rate by increasing lesion size should be a relatively non-controversial endeavor that most people can agree on.

The physics of radiofrequency ablation

Traditional thermal RFA involves the use of high-frequency alternating current (300 000–500 000 Hz), which results in ionic agitation and friction generating focal heating in tissue (ie, the tissue surrounding the electrode becomes the primary source

Table 10 Factors affecting radiofrequency lesion generation

Radiofrequency element	Electrophysiological principle
Distance from active tip	Heat generation=1/(radius from active tip)[220] ► Tissue heating decreases rapidly with increasing distance from the active tip.
RFA current intensity*	Heat generation=(current density)[14] ► Heat generated from RFA is directly proportional to current density. ► Current intensity has a strong influence on tissue heating.
Duration of RF application	The duration of heating influences lesion size.

*Tip size as determined by the gauge of the needle and the length of the active tip influences RF current intensity.
RF, radiofrequency; RFA, radiofrequency ablation

of the heat). Irreversible cellular damage can occur from focal temperatures above 42°C, although for most mammalian tissues damage occurs between 46°C and 49°C.[225 226] Such temperatures applied to a nerve result in local destruction and Wallerian degeneration of nerve axons.[226] Although both impedance-controlled and temperature-controlled systems exist, for interventional pain medicine temperature-controlled RFA systems are typically employed. The 'bio-heat' equation governing RF-induced heat transfer through tissue was initially described over 70 years ago by Pennes,[227] and has since been simplified as follows[228]:

Coagulation necrosis=(heat generated×local tissue interactions)–heat lost

The ability to ablate specific tissues while limiting destruction to non-targeted tissues depends on local physiological tissue characteristics and factors that influence energy delivery. In a simplified thermal RFA system, three primary factors determine heat generation and lesion size (table 10): distance from the cannula's active tip, RF current density and duration of current application.[229–231] Specifically, peak power and total energy delivered directly correlate with lesion size.[232] Duration of RF application affects lesion size and influences lesion variability.[233] Although a substantial amount of lesion growth occurs within the first 60 s after the set temperature (eg, 80°C) is achieved (~87% of the maximal surface area), lesion growth continues after this threshold is surpassed. Consequently, as the lesioning time increases lesion size variability decreases.[233]

Methods to enhance lesion size

Multiple methods have been studied to increase lesion size in both in vivo and ex vivo models. It is important to recognize that studies performed in ex vivo models do not necessarily simulate in vivo conditions (ie, may have different tissue properties). When examining ex vivo and in vivo models used to assess lesion size, it is imperative to understand the medium in which the testing was performed. For example, substantial differences exist between fluid egg white and solid animal tissue.[234] Although egg white heats faster than muscle, lesions performed in egg white typically underestimate lesion size and are not consistently reproducible.[230 234] Ex vivo models of RFA lesion size can also underestimate in vivo lesion size secondary to the lower baseline tissue temperature.[232 235 236] The lower baseline temperature requires higher energy deposition to attain the same ablation zone. The presence of bone also alters lesion geometry, with the maximal effective radius approximately doubling against bone compared with a muscle-only model.[237]

In clinical practice, common techniques that have been shown to enhance tissue ablation include increasing the set temperature, increasing the diameter of the electrode cannula, increasing size of the active tip and increasing lesion time. The major limitation of high temperatures is disruption of conductivity at the electrode-tissue interface. When tissue boils, desiccates or chars, it becomes a high impedance insulator, which may result in an RFA generator fault and/or a smaller lesion size. The temperature at which this takes place, known as the 'electrode interface disruption temperature', typically occurs near 100°C.[218] Therefore, with traditional systems, increasing set temperature beyond 90°C is not recommended.

Perhaps the most efficient and reliable means to amplify lesion size is to increase RF cannula diameter. For example, when the cannula diameter is increased from 22-gauge to 16-gauge at RFA settings of 80°C and 2 min, the average lesion width increases 58%–65%, which correlates to a lesion that is 3–4 mm larger. Similarly, increasing lesion time from 1 to 3 min, without changing cannula size or temperature, results in a lesion that is 23%–32% larger.[230]

Additional methods that can be used to increase lesion size include fluid pre-injection, modification of the electrode tip and the use of internally cooled electrodes ('cooled RFA').[218 232 233 238 239] For internally cooled electrodes, an internal perfusate serves as a heat sink that removes heat closest to the electrode. Therefore, heating of the tissue nearest to the electrode is reduced and greater current deposition occurs, resulting in larger lesions.[240] Significant tissue ablation occurs distal to the tip of the cannula with internally cooled electrodes, whereas standard electrodes produce minimal lesioning beyond the cannula tip.[241]

Fluid modulation

Both ex vivo and in vivo data with traditional thermal RFA have demonstrated amplification of lesion size with the injection of increasing concentrations of saline.[232 233 238 239] Based on the Bioheat equation, injecting specific fluids modulates local tissue interactions. The pre-injection of hypertonic saline (ie, saline with concentration >0.9%) increases conductivity (thereby decreasing resistance), resulting in higher peak power and total energy output. In vivo data demonstrate that when 1 mL of 8% saline is injected after 1 mL of 1% lidocaine prior to RF lesioning, the lesion width increases by >3 mm, and the calculated volume increases by >50%, in comparison to no additional fluid.[232] The pre-injection of hypertonic saline also alters the histological composition, increasing to the largest degree the size of the outermost ablation zone, which is associated with coagulative necrosis and edema.[232 242 243] When injecting hyperosmolar solutions such as hypertonic saline, caution must be exercised to minimize inadvertent spread to non-targeted neural tissue because of theoretical concerns for neurotoxicity[244]. The geometry of the RFA lesion associated with NaCl pre-injection is altered as well, with the maximum width of the lesion shifted more toward the distal end of the active tip.[232]

In ex vivo models, saline solutions, and other solutions have been shown to enhance lesion size with traditional thermal RFA, with more conductive solutions (ie, less impedance) having a greater effect.[239 245] For example, the pre-injection of 1% lidocaine in 0.7% NaCl, which is often used to increase procedure tolerability, has been shown to increase the area of ablation in ex vivo models.[238 239] However, this relationship was not reproduced in an elegant in vivo experiment examining the effect of pre-injection fluid on lesion size using traditional thermal RFA.[232] Conversely, the pre-injection of corticosteroids prior to lesioning has been shown to reduce lesion size.[246]

When using internally cooled electrodes, fluid modulation using LA and NaCl concentrations of 0.9% and 7.3% have not been shown to increase lesion size.[240 247]

There are theoretical reasons to increase lesion size for lumbar RFA, including optimizing the chance of incorporating the targeted structure into the area of tissue ablation, and possibly increasing the duration of pain relief; yet, no clinical data exist to verify these assumptions. Whereas anecdotal evidence suggests robust treatment effects when lesion-amplifying techniques are used, comparative-effectiveness studies are needed to confirm these observations.

Larger lesions and duration of benefit

The effect of larger lesions on duration of pain relief in individuals with a successful outcome is unclear. It is not entirely understood how RFA exerts its benefit, but it may occur via damaging nerves such that they cannot transmit nociceptive information, or transecting the nerves; in one review, it is postulated that RFA results in third-degree peripheral nerve injury to the myelin, axon and endoneurium without disrupting the fascicular arrangement.[248] If analgesia resulted from complete nerve bisection, nerve regrowth would not be expected to occur faster with a larger transected area, provided the nerve was completely severed in both scenarios and Wallerian degeneration occurred. If larger lesions resulted in a greater likelihood of completely transecting a nerve rather than axonotmesis, then that could theoretically result in a longer duration of benefit. In one placebo-controlled study that examined the duration of pain relief with internally cooled RFA, which results in a larger lesion diameter than traditional RFA, the authors reported a mean duration of relief of 7.9 months after lateral branch RFA for SI joint pain.[241] The lack of longer pain relief in this study compared with that achieved with conventional RFA may be due to the nerves targeted (the SI joint is more extensively innervated, and requires more ablations, than lumbar facet joint pain), the blinding of participants and close surveillance, or myriad other factors, and warrants further examination of this issue.

Risk mitigation

When creating larger lesions, care must be taken to avoid collateral damage to surrounding tissues. One of the most feared complications is damage to surrounding non-targeted spinal nerves.[249] Methods to prevent this complication include precise anatomic placement of the RFA cannula with fluoroscopic imaging checked in multiple views, physiological testing with sensorimotor stimulation and a detailed understanding of lesion dimensions. In addition, the risk of toxicity to non-targeted tissues, including central and peripheral nervous system structures, should be considered before injecting specific fluids (ie, high saline concentrations).

Recommendations

Based on the current limitations of traditional thermal RFA and the small size of the targeted structures (ie, lumbar medial branches and dorsal rami), creating larger lesions with reduced lesion variability may increase the likelihood of capturing the targeted structure. If larger lesions are used, care should be taken to limit damage to non-targeted structures; grade C recommendation with low level of certainty for using larger lesions to improve the ability to capture the targeted nerves; grade I with low level of certainty for the ability of larger lesions to increase the duration of pain relief.

QUESTION 13: SHOULD ELECTRODES BE POSITIONED IN A CERTAIN ORIENTATION, AND IF SO, WHAT IS THAT ORIENTATION?

Background

Relief of lumbar facetogenic pain by thermal RFA of the medial branch rests on the premise that pain transmission can be interrupted if the nerve is coagulated by heat.[250] One might infer that if a longer a section of the nerve is destroyed, longer pain relief may ensue because it takes more time for the injured nerve to regain the ability of pain transmission. In humans, nerve regrowth occurs at a variable rate, from 1 to 2 mm per day in small nerves, and up to 5 mm per day in larger nerves, with factors such as electrical stimulation, less scar tissue, hormonal factors, favorable genetics, shorter distance of the origination of the nerve to the lesion site, and exercise enhancing regenerative ability.[251–253] However, when a nerve is completely severed (which may or may not happen with RFA), Wallerian degeneration distal to the lesion occurs, such that the width of transection plays a relatively minor role in regrowth. Currently, there are two prevailing methods to achieve medial branch ablation, which differ based on the orientation of the placement of electrodes. According to the one technique, curved electrodes are inserted tangentially along the course of the nerve, allowing longitudinal contact between the cannula and nerve; if the curved tip is rotated, a further increase in lesion size is realized.[254] This technique has been described as 'parallel', although geometrically this term refers to two lines extending in the same direction, everywhere equidistant and never meeting. In one variation of the parallel technique, a large, straight cannula is inserted at a steep caudo-cephalad angle, approximately 20° in a lateral to medial direction, allowing the electrode to embrace the anterolateral aspect of the base of the superior articular process. In the perpendicular technique, cannulas are inserted using an oblique fluoroscopic view perpendicular to the course of the nerve, such that the length of the active tip is less important.[254] Is one method better than the other? The following discussion is restricted to conventional thermal RF medial branch ablation, as the use of internally cooled electrodes, which generate a circular lesion that extends distal to the electrode tip (approximately 40% of the lesion occurs distal to the tip) rather than a spherical lesion that envelops the electrode, are typically inserted in a perpendicular fashion to optimize lesion characteristics and minimize tissue trauma.

Anatomy

The lumbar facet joints are paired, true synovial joints.[255] Each joint is innervated by the medial branches of the primary dorsal rami from that level and the level above (figure 1). The L1-L4 medial branches of the dorsal rami run across the superior portion of the subjacent transverse process, under the mamillo-accessory ligament at the junction of the superior articular process and the root of the transverse process, and then course onto the lamina. On the lamina the nerve divides, giving off branches to the joint below, the joint at that level, the interspinous ligament and muscle and the multifidus muscle. For the purposes of medial branch neurotomy, the nerve can be considered to hug the superior articular process by the mamillo-accessory ligament. In some people, the nerve may be trapped beneath a calcified ligament, which occurs most commonly at the fifth lumbar vertebra, but can occur at more cephalad levels.[184] At L5, it is the dorsal ramus itself that is amenable to ablation, which runs in the groove between the superior articular process of S1 and the sacral ala (figure 1A-C).[255]

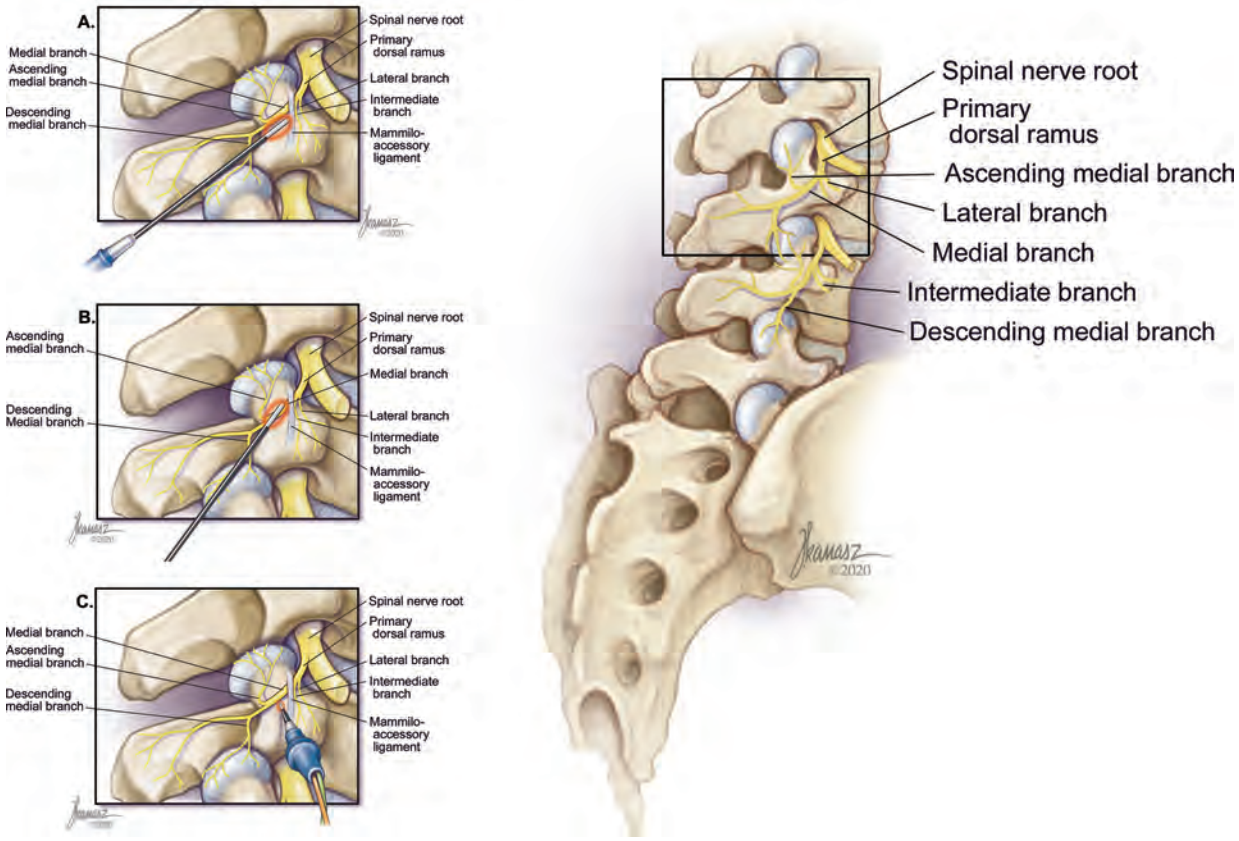

Figure 1 Representational drawing depicting the lumbosacral facet joints and accompanying neural anatomy. Insets illustrate closeup views of the bony and neural anatomical landmarks and a schematic representation of the effect electrode orientation has on nerve ablation. Artistic renditions by Joe Kanasz (joekanasz@att.net). (A) Parallel insertion of electrodes. Parallel placement may result in a higher likelihood of missing the nerve than with near-parallel orientation. (B) Near-parallel insertion of electrodes. This may result in the highest likelihood of medial branch nerve ablation. (C) Perpendicular insertion of electrodes. This theoretically results in the highest chance of missing the nerve, which may be more likely when the medial branch is entrapped beneath the mammilo-accessory ligament.

History and preclinical studies

The concept of denervation of facet joints has undergone much evolution since it originated from the neurosurgeon Rees's technique that described severing the articular nerves supplying the zygapophysial joints through surgical incisions.[256] A less traumatic approach, using RF electrodes, was subsequently described by another neurosurgeon, Norman Shealy.[257] He recommended placing the electrodes lateral to the articular processes with the tip of the electrode reaching the intertransverse ligament. Subsequently, a cadaveric study by Bogduk and Long[258] found that it was the medial branches of lumbar dorsal rami and not articular branches that should be targeted, which led to major changes in electrode positions.

In the early days of RFA, it was common practice to place electrodes perpendicular to the target nerve(s). However, further investigations were prompted by varying degrees of success and short-lived pain relief.[257] Experimental lesions were created in egg white and meat using 18-gauge electrodes heated to temperatures of 80° and 90°C. In egg white, lesions extend slightly proximal to the active tip, but never distal. Lesion expansion occurs in the radial direction, circumferentially around the electrode in an oblate spheroid shape. In meat, the tissue surrounding the active tip is denatured longitudinally in an elliptical shape, with the lesions extending for a short distance distal to the electrode tip. Such observations were confirmed by other independent investigators.[230 238 259 260] This led researchers to conclude that electrodes inserted parallel to the course of the nerve were more likely to envelop the target, and that inserting the electrodes in a perpendicular trajectory can lead to non-capture and clinical failure (partial relief or limited duration of benefit).

Eckmann *et al*[237] reported that lesions created ex vivo in muscle, and especially egg white, do not represent physiological conditions during in vivo medial branch ablation, whereby the electrode is placed adjacent to bone and surrounding soft tissue. The authors conducted an experiment by placing the electrodes either apposed to bone with muscle on the other side or fully embedded in muscle. In the bone-muscle model, they found that the lesions remained elliptical with the long axis aligned with that of the electrode. Yet the lesions expanded to a greater extent perpendicularly from the needle axis when compared with those created in pure muscle. The authors did not draw conclusions about how their findings could be used to optimize lesion size in vivo, although they suggested that placing an electrode perpendicular to the nerve would result in a larger horizontal lesion on bone than would be expected in a pure muscle model.

In a cadaveric study, Lau *et al*[261] placed electrodes either parallel or perpendicular onto the L4 medial branch and L5 dorsal ramus nerves in situ under direct vision. Radiographs of anteroposterior, lateral and declined views were taken. Ellipses were drawn based on the average size of lesions generated and expressed as electrode-widths. Investigators observed that the nerves might not be captured by lesions produced by electrodes

oriented perpendicular to the targets, because the nerves were situated at the tapering end of the elliptical lesions. To improve the likelihood that the nerves are incorporated into RF lesions, they recommended that electrodes be placed parallel to the nerves, against the neck of the superior articular process.

Theoretical issues

Transecting a nerve anywhere results in Wallerian degeneration distal to the lesion location.[262] Similar to cutting down a tree trunk or branch with a chainsaw, orienting the instrument used to cut the nerve perpendicular to the target in the same plane should theoretically maximize the chance of a complete transection (which may or may not be necessary for analgesia). However, the distance between the area of needle insertion (ie, skin) and the bony target (ie, the junction between the superior articular and transverse processes), and the posteriorly concave curvature of the transverse processes, preclude this. Theoretically, if an electrode could be inserted in the same plane as a target nerve, and a lesion extended circumferentially around the electrode tip, then positioning the electrode parallel to the nerve would actually minimize the likelihood of nerve ablation. In order to maximize lesion area on bone, where the medial branches reside, the electrode should ideally be inserted in a medial-cephalad direction, obliquely parallel to the nerve course. This could also result in a higher likelihood of nerve ablation in cases where the medial branch is trapped beneath a calcified mamillo-accessory ligament.[184]

The use of curved electrodes has recently gained popularity for lumbar medial branch RFA, whereby the depth from skin to the transverse process precludes positioning the electrode juxtaposed on bone, unlike with a posterior approach in the cervical spine. In order to maximize the lesion area on bone where the medial branches reside, practitioners typically position the convex surface of the curved active tip anteriorly on the transverse process.[18] To further enhance the lesion area, many doctors will then advance the cannula and rotate it 180°, such that the concave surface hugs the inferior part of the posterior foraminal wall. Although this makes intuitive sense, there are no studies to support or refute this practice.

Comparison of parallel versus perpendicular electrode orientation on RFA outcome in clinical practice

Only one study to date has addressed the effect of electrode placement on the outcome of lumbar medial branch ablation. Loh *et al*[263] performed a single-center, retrospective chart review in 323 patients comparing two different techniques used by multiple practitioners over a 4-year period. A perpendicular approach, in which cannulas were inserted perpendicular to the medial branch in a different plane targeting a point on the transverse process just caudal to the supero-medial edge of the transverse process, was used in 241 patients. A later technique, which used near-parallel electrode insertion, was employed in 82 patients. The authors reported lower pain scores (mean 3.64 vs 4.27; p=0.06) at 1-month postprocedure and a longer duration of relief (median duration 4 vs 1.5 months; p=0.02) in patients who received near-parallel electrode placement. However, differences in selection criteria, technical parameters and patient expectations (ie, different physicians use different approaches) limit the generalizability of these results.

In another retrospective study performed in the cervical spine, Cheng *et al*[264] found no difference in pain reduction at 1 and 3 months following RFA between individuals treated using perpendicular (ie, lateral approach) electrode insertion (n=38) and those who were treated using a parallel (ie, from the posterior neck) approach (n=44), but those treated using the lateral approach fared better at 6 and 12 months. Along with the anatomical differences between the cervical and lumbar spine regions, the same limitations in the study by Loh *et al*[263] undermine external validity in this study which was never published in a peer-reviewed journal.

Indirect comparisons of outcomes in studies using different approaches

The two placebo-controlled trials that used parallel electrode insertion both yielded positive results,[82 83] while only one[81] of three[19 81 84] that inserted the electrodes perpendicular to the targeted nerves reported positive findings. The negative, randomized MINT study[17] was also widely criticized for using a perpendicular needle approach.[25–27] However, the heterogeneity of the patient populations, and differences in selection criteria, other technical aspects of RFA (eg, fluid modulation, cannula size, lesioning temperature and duration) and outcome measures preclude any meaningful conclusions from indirect comparisons of electrode insertion.

Recommendation

Based on anatomical descriptions and the available literature, near-parallel placement of traditional (eg, non-internally cooled and variations designed to increase lesion area) electrodes is recommended to increase the likelihood of medial branch nerve RFA by increasing the margin of error; grade B evidence, low level of certainty (figure 1).

QUESTION 14: SHOULD SENSORY AND/OR MOTOR STIMULATION BE PERFORMED BEFORE RADIOFREQUENCY ABLATION?

Rationale for sensory stimulation and evidence

The success of RFA of lumbar medial branch nerves is dependent on correctly identifying patients whose pain is mediated via the medial branch nerves and by providing a thermal lesion that adequately coagulates the nerves, thereby preventing conduction of nociceptive information along the nerves. Integral to this second point is that the RF cannula must be in close enough proximity to the intended target nerves to result in ablation. Additionally, to avoid or minimize complications, the procedure should avoid coagulation of the ventral ramus or other unintended structures. Although some physicians believe that these goals can be accomplished through appropriate needle placement to the intended anatomical target based on fluoroscopic landmarks, others advocate for the use of sensory and/or motor testing in addition to anatomic landmarks to achieve optimal placement. The justification for this is based on anatomical variations in the location of the medial branches and the multiple articular branches emanating from each nerve.[261 265–267]

Sensory stimulation is typically carried out at 50 Hz. Patients are asked to inform the treating physician when they identify a sensory change (eg, tingling, buzzing, vibration, pain). Traditionally, an acceptable threshold is ≤0.5 V.[7 18 81 84] If sensory threshold is in fact being used to determine optimal placement, however, the cannula should be advanced in all three dimensions (anterior-posterior, cephalad-caudal and medial-lateral) to determine exactly where the stimulation threshold is lowest. In clinical practice, most physicians do not modify placement once an acceptable threshold is reached. Additionally, sensation may be evoked by local muscle stimulation even when the nerve is not close enough to be incorporated into a thermal RF lesion.

This is particularly true since the shape of the lesion is known to extend circumferentially along the active tip. In this regard, suboptimal needle placement technique (perpendicular rather than parallel trajectory) can result in adequate sensory stimulation while the lesion may be insufficient for coagulation of the nerve and relief of pain. A prospective study in 61 patients who underwent lumbar facet RFA after a positive block found no correlation between average sensory threshold and treatment results.[268] However, the authors concluded that because sensory testing was optimized for each patient by adjusting the electrode in multiple planes before lesioning, the results should not be misinterpreted as meaning sensory testing should not be done. Rather, sensory testing is just one of many factors that include age, gender, genetics, sedation and baseline analgesics and comorbidities (eg diabetes) that could affect medial branch sensory perception. In a small observational study by Dreyfuss *et al*,[147] the authors found no correlation between the degree of multifidus muscle atrophy and treatment outcome or levels treated 17–26 months after denervation. In two small placebo-controlled studies performed in the cervical and lumbar spine that yielded positive results, the investigators did not use sensory testing, instead creating four to six empirical lesions per level based on anatomic landmarks.[82 212]

Rationale for motor stimulation and evidence

Improvement of efficacy

Motor stimulation is usually performed at a 2 Hz frequency. There are two potential uses for motor testing: (1) to identify multifidus or other paraspinal muscle stimulation indicating proper placement[23] and (2) to identify distal muscle contraction when the needle is in dangerous proximity to the ventral ramus or spinal nerve. In a prospective audit by Dreyfuss *et al*,[23] multifidus muscle stimulation without sensory stimulation resulted in a success rate of 87% 12 months post-RFA. A retrospective study by Koh *et al*[269] provides guarded support for the assertion that motor stimulation may be used to ensure proximity to the targeted nerve. They stratified 68 patients who underwent lumbar medial branch RFA into three groups: complete twitching elicited (observation of paravertebral muscle contraction at all levels), partial twitching elicited (paravertebral muscle contractions observed at one or two levels) or no twitching elicited. In the 'no-twitch', 'partial twitch' and 'complete twitch' groups, the mean durations of benefit were 4.6, 5.8 and 7.0 months, respectively, with the proportion of successful procedures at 6 months being statistically greater in the 'complete twitch' than the 'no-twitch' group.

It is important to recognize that at L5, it is the dorsal ramus itself that is targeted, so motor stimulation should elicit visible contractions of the spinalis, longissimus and iliocostalis muscles. However, in practice, the elicitation of paravertebral muscle contractions is typically less prominent at L5. There are several explanations for this, including that at L5 it may be the medial branch (rather than the dorsal ramus) that is being denervated in some patients, that at higher lumbar levels it may be the dorsal ramus itself (rather than the medial branch) being lesioned in some patients, or that other factors are at play (eg, greater adipose tissue obscuring contraction, or greater atrophy at L5).

Enhanced safety

In some cases, eliciting muscle contraction may provide false confidence in needle placement when the motor nerve being stimulated does not actually innervate the facet joint (ie, cases of aberrant, non-medial branch innervation).[127] For the purposes of enhancing safety, practitioners typically increase the voltage to 1.5–2 V, or three times the sensory stimulation threshold for motor testing.[270] The motor stimulation threshold may be important in preventing complications, as one case report described a patient who suffered an L5 sensory radiculopathy following L3–L5 dorsal ramus denervation whereby motor testing was not conducted above 1 V.[249] If no muscle contraction in the appropriate myotome is identified, most practitioners believe it is safe to proceed. After motor stimulation testing is completed, some systems require the electrode to be removed while LA is administered, which can result in inadvertent needle movement. In these cases, comparative images before and after anesthetic injection should be obtained to ensure the electrode position is identical. Additionally, many newer systems have a separate port that allows for the injection of LA without removing and replacing the electrode, which should obviate the need for additional images or testing. It is noteworthy that the SIS guidelines[250] on RF neurotomy do not endorse motor stimulation before lumbar facet RFA, asserting that multiple fluoroscopic views and monitoring patients for lower leg pain are sufficient to prevent nerve root injury. However, there is at least one reported case of permanent dropped head syndrome occurring weeks after cervical RFA when motor stimulation was not performed, although the etiology and causal relationship to the procedure remain unclear.[271]

Recommendations

In summary, we recommend sensory stimulation when single lesions are anticipated; grade C, low level of certainty. When multiple lesions are planned, the evidence for sensory stimulation is inconclusive; grade I, moderate level of certainty. For motor stimulation, we find that it may be beneficial for both safety and effectiveness purposes; grade B, low level of certainty.

QUESTION 15: WHAT ARE THE MOST COMMON COMPLICATIONS OF FACET INTERVENTIONS, AND HOW CAN THEY BE MINIMIZED?

Background

Diagnostic MBB and RFA of the nerve supply to the lumbar facet joints require placement of needles or RFA cannulas on the posterior elements of the lumbar vertebral column under image-guidance. The needles (22-gauge to 25-gauge) or RF cannulas (16-gauge to 22-gauge) are placed at the junction of the superior articular and the transverse processes of the vertebra. The temperature generated at the tip of the cannula is usually between 80°C and 90°C and heating is generally performed for 1 to 3 min. The risks from this procedure can be broadly classified as: vascular penetration and injury, procedure-related pain and dysesthesias, injury to non-target neural structures in proximity to the RFA probe, consequences of denervating surrounding muscles and impact on implanted electrical devices including pacemakers, cardioverter defibrillators, deep brain and spinal cord stimulators and spinal instrumentation.

Vascular penetration and injury

Vascular penetration and injury are possible during lumbar MBB and RFA procedures. The incidence of intravascular positioning of the needle tip during lumbar MBB varies from 3.7% to upward of 20%.[106 127 143 272–274] In a study of 1433 lumbar MBBs performed in 456 patients, an incidence of 6.1% for vascular uptake was noted.[272] Approximately one-third of these were identified by aspiration prior to injection, with the rest recognized on fluoroscopy following injection of contrast

agent. Vascular penetration with or without the injection of LA is likely to result in a false-negative diagnostic block because of washout of the LA. In a study by Kaplan *et al*[127] conducted in 18 volunteers, 6 subjects experienced vascular uptake during MBB (5 at one nerve, 1 at two nerves), with half of these individuals retaining the ability to perceive subsequent capsular distention (ie, possible false-negative block). Intravascular injection of LA is unlikely to cause harm because of the low volume administered, and the low probability of the presence of radicular 'feeder' vessels in the vicinity. Aspirating for blood prior to injection has high specificity (97%; 95% CI 95.6% to 98.4%) but low sensitivity (41%; 95% CI 29.2% to 53.7%), making it a poor screening tool.[274] When contrast is injected, it should ideally be performed using real-time fluoroscopy, as spot radiographs have a 59% sensitivity compared with live contrast injection.[272] However, digital subtraction angiography is considered the reference standard for vascular uptake. In a study involving 344 diagnostic MBBs, the authors found a 19% incidence of vascular uptake with digital subtraction, compared with 11% with real-time contrast administration and 6.7% with aspiration.[106] The type of needle can also affect intravascular uptake during MBB, with one study showing a lower incidence with a pencil-point than a cutting needle (pencil-point needles may also carry a lower incidence of backache, which could result in a lower false-negative rate).[274 275] Guidelines endorsed by SIS also recommend pre-injection of contrast with low volumes, between 0.1 and 0.3 mL, in order to detect venous uptake and ensure the adequacy of spread.[16]

A study that reported on complications from 3162 MBBs found superficial bleeding or hematomas in 0.1%–0.4% of the patients.[273] Lumbar MBB and RFA are currently classified as 'low-risk' procedures in the guidelines on spinal procedures in patients on anticoagulant and antiplatelet medications formulated collaboratively by the American Society of Regional Anesthesia and Pain Medicine (ASRA) and other societies.[276] This risk classification was based on a study by Endres *et al*[277] that reported a 0% complication rate in 1836 patients who continued their anticoagulant therapy. Whereas no bleeding complications were observed among individuals who continued their anticoagulant therapy, a total of nine adverse events were reported among the 2296 patients who discontinued their anticoagulant therapy. An earlier survey study conducted among 325 members of ASIPP found that thromboembolic events were three times more likely than bleeding complications after interventional spine procedures. These events were more severe and common when anticoagulants were discontinued, while there was no difference in the reported occurrence of bleeding complications stratified by whether or not anticoagulants were continued.[273] Based on the literature, the ASRA anticoagulation guidelines committee placed thoracic and lumbar MBB and RFA in the low-risk procedure category, especially in patients who are at a high risk of thromboembolic events. This is consistent with guidelines from the SIS,[278 279] and represented a change from the previous version of the ASRA guidelines issued in 2015, in which thoracolumbar procedures were classified as 'intermediate risk'.[280] However, the SIS guidelines acknowledged the limited data on bleeding complications when large-bore cannulas are employed for denervation. The ASRA and SIS committees further recommended that MBB and RFA procedures be performed with imaging guidance in multiple planes, with special attention to lateral views to ensure that the needle is not advanced into the vicinity of the vascular structures in the neuroforamen.

In 2019, ASIPP published anticoagulation guidelines that placed lumbar facet IA injections, MBB and RFA in the moderate risk category.[281] ASIPP's guidelines allow for continuation of aspirin, antiplatelet agents and platelet aggregation inhibitors for moderate-risk procedures, although they recommend discontinuing vitamin K antagonists, thrombin inhibitors, heparin and antifactor Xa medications.

Recommendations

The committee recommends checking for intravascular placement of the needle tip by aspirating and visualizing the spread of contrast on fluoroscopy in real-time prior to performing MBB to reduce false-negative results. This should ideally be done in a manner such that the total injectate dose (LA and contrast) is kept as low as possible to minimize the effect on LA dispersion; grade C recommendation, low level of certainty.

The committee also recommends that non-heparin anticoagulants be continued in the peri-procedure period for patients undergoing MBB or RFA, especially in patients at high risk of thromboembolic complications. Healthcare providers considering discontinuation of anticoagulants should consult with the physician prescribing these medications, and discuss these recommendations with the patient (ie, shared decision model) prior to making any changes; grade B recommendation, moderate level of certainty.

RFA-related pain and numbness

RFA of the lumbar MBB can be associated with tenderness, pain, hypoesthesia or dysesthesia and limitations of movement due to the thermal lesion around the target nerves. Release of pro-inflammatory cytokines is one postulated mechanism for post-procedural discomfort. Neuropathic pain in the skin overlying the lumbar paraspinal muscles possibly resulting from transection of the lateral branches of the lumbar dorsal rami during lumbar facet RFA was first reported in 1981.[282] A retrospective chart review of 116 RFA procedures performed in 92 patients reported an incidence of 3.3% for localized back pain lasting >3 weeks.[283] In an observational study of 34 patients, localized pain lasting up to 1 week after the procedure was reported in all patients, with 6 reporting back numbness for up to 3 weeks.[284] In a prospective study comparing two approaches with cannula placement for lumbar medial branch RFA in 68 patients, 6 patients (8.8%) reported persistent back pain after the RFA, with 3 having features of neuropathic pain that lasted longer than 3 months.[285]

These adverse effects are usually minor and self-limiting, although several studies have sought to identify ways to prevent them. Dobrogowski *et al*[286] performed an RCT comparing the impact of administering 10 mg of pentoxifylline, 10 mg of methylprednisolone acetate (MPA) or saline following RFA of the lumbar medial branches but prior to removal of the RFA cannula in 45 patients. The authors reported a significant decrease in local tenderness and postprocedure soreness in patients who received pentoxifylline or MPA, but not in those receiving saline. In the saline group, 26.7% of patients had severe local tenderness 1 week after the procedure which disappeared in three of four individuals by 1 month. No patients in the MPA or pentoxifylline groups reported severe tenderness after the procedure.[286] However, a more recent retrospective study performed in 164 patients who underwent lumbar medial branch RFA found no difference in the incidence of postprocedure neuritis between individuals who received postneurotomy steroids (6.4%) compared with those who did not (6.9%).[287] Of note, an ex vivo study found that injecting steroids with LA prior to RFA can reduce lesion size.[246]

Recommendations

The committee recommends that physicians inform patients about the common adverse effects of RFA including pain, dysesthesias and numbness lasting from a few days to a few weeks following lumbar facet joint denervation. Injection of steroid through the cannula after ablation but prior to its removal may reduce pain and discomfort following RFA; grade C recommendation, low level of certainty.

Injury to spinal cord or nerve roots

Injury to the spinal cord (upper lumbar procedures) or nerve roots after lumbar facet RFA is possible but rare. The spinal nerve, and especially the dorsal root ganglion, is in proximity to the target site for medial branch neurotomy. Anterior misplacement of the electrode into the neuroforamen can result in the active tip of the RF electrode being situated near the nerve root. A case report described new sensory symptoms in the dermatomal distribution of the fifth lumbar nerve following RFA of the third to fifth lumbar medial branches and dorsal rami.[249] Another study that reported on complications from 3162 MBBs found irritation of the nerve roots occurred in 0.1% of the patients, but found no long-term neural deficits.[273] Sensory and motor stimulation to reduce the probability of proximity of the RF cannula tip to the spinal nerve root traversing in the foramen have been advocated for preventing injury to the spinal nerves, but the evidence is inconclusive.

Recommendations

The committee recommends the use of true anteroposterior, ipsilateral oblique ('Scotty-dog') and true lateral views on fluoroscopy during placement of RFA cannulas to ensure that the tips are outside of the neural foramina. Absence of sensorimotor responses in a radicular distribution in response to test stimulation prior to RFA may also reduce the probability of injury to the spinal cord and spinal nerve roots; grade B recommendation, low level of certainty.

RFA-related degeneration of spinal anatomy and musculature

The multifidus muscle, the most medial of the deep intrinsic spinal muscles, contributes to segmental stability in the lumbar spine.[288] RFA of the medial branches innervating the lumbar facet joints results in denervation of this muscle, but the physiological implications of this phenomenon are unclear. Dreyfuss *et al*[147] conducted a study on five patients who had undergone unilateral lumbar RFA. MRI of the lumbar spine was performed 17–26 months after denervation. Diffuse atrophy of the lumbar multifidus was noted in all patients, but was not limited to the levels of RFA even though post-RFA electromyography indicated denervation of multifidus muscles only at the levels where RFA was performed. None of the patients had recurrence of pain or evidence of spinal instability.[147] In a larger case series of 27 patients, MRI was done prior to and following lumbar RFA to assess the bulk of the multifidus, and for evidence of disc and facet joint degeneration.[289] No change in muscle mass or degeneration of the facet joints was observed, although a greater amount of disc degeneration was noted compared with unaffected levels (14.9% vs 4.6%).

It is important to note that at the level of the fifth lumbar vertebra, it is the dorsal ramus itself that is targeted. Based on characteristic innervation patterns, this should result in segmental denervation of the iliocostalis (a component of the erector spinae muscle), which is involved in back extension through lateral branch innervation, and the longissimus muscle (another component of the erector spinae muscle), which helps maintain an erect spine and contributes to lateral flexion, and is innervated by the intermediate branch. However, the stronger contractions that are typically observed at the second to the fourth lumbar vertebral levels suggest that, at least in some people, the iliocostalis and longissimus muscles may also be stimulated during motor testing, and denervated during ablation. This hypothesis is supported by unpublished data showing that it is the contraction of the longissimus and iliocostalis muscles during facet joint nerve motor stimulation that is most prominent (unpublished data from Avanos, personal communication from Jeffrey Petersohn), and a case report demonstrating denervation of both the multifidus muscle and erector spinae muscle groups after lumbar facet RFA.[290] Finally, loss of paraspinal extensor muscle action has been reported following multilevel, unilateral RFA for denervation of the upper cervical facet joints. This patient required surgical stabilization of the cervical spine.[271]

Recommendations

The committee recommends a comprehensive discussion with patients about the potential short-term and long-term impact of lumbar facet joint RFA on spinal anatomy. It should be explained to patients that morphological changes to spinal muscles will not result in adverse clinical outcomes in most patients. However, recommending PT regimens aimed at restoring the function of paraspinal muscles prior to and after RFA may improve outcomes; grade C recommendation, low level of certainty.

Impact of RFA on existing implanted devices

Monopolar RFA of innervation to lumbar facet joints involves the use of electrical current that emerges from the tip of the RF cannula and flows through the body before exiting through the grounding pad. Magnetic fields created from use of shortwave diathermy can result in interference with functioning of implanted electric devices such as deep brain[291] or spinal cord stimulators. There is some evidence that bipolar RFA may be safer than monopolar.[292] However, safe use of monopolar RFA has been reported in a patient with deep brain stimulators with one of the implanted pulse generators located in the anterior abdominal wall.[150] Safe and successful bipolar RFA to treat cervical and lumbar facetogenic pain in two patients with automated implantable cardioverter defibrillators has also been reported.[292] When the grounding pad is placed on the lower extremity, lumbar RFA should theoretically carry a lower risk of device interference than for procedures performed in the neck. The American Society of Anesthesiology recommends that the grounding electrode be placed at least 15 cm away from pacing leads for both permanent pacemakers and implantable cardiac defibrillators.[293]

Use of bipolar RF mode may be preferable to unipolar for risk minimization because of the smaller induced electromagnetic field. If using unipolar RF, placing the grounding pad close to the neurotomy site will reduce the size of the induced electromagnetic field. This will minimize the risk of heating the neurostimulator battery and electrodes. However, placing the grounding pad too close to the neurotomy site can increase the risk of tissue burns, particularly when using high current, long activation times, and the use of conductive fluid, since the energy has less tissue through which to dissipate.

Recommendations

Healthcare teams responsible for managing the implanted device (eg, neurology, cardiology, pain medicine) should be consulted

regarding the planned RFA procedure. If RFA is performed, implanted electrical devices such as neurostimulators should be programed to an output of zero volts and turned off before the procedure, and the risks of device damage discussed with the patient. For pacemakers and defibrillators, the cardiology team and device manufacturer should be consulted prior to facet joint medial branch RFA, and their recommendations followed (eg, program pacemaker to asynchronous mode). Using no or judicious sedation will allow the physician to communicate effectively with the patient and to detect any potential injury to the central nervous system or cardiovascular decompensation at an early stage. A deactivated neurostimulator should be turned on following the RFA procedure and reprogrammed to preprocedural settings; grade C recommendation, low level of certainty.

Tissue burns

Skin burns from either extension of the lesion into the dermis or equipment malfunction (eg, electrical faults, insulation breaks in the electrodes, generator malfunction or incorrect application of the electrical dispersive (aka grounding pad)), have been reported.[294–297] Skin burns resulting from direct extension have been described in areas such as the knee where there is less tissue between the target nerve and the skin, and may be more likely to occur with larger lesions.[294] Although RFA in the back is extremely unlikely to result in skin burns in even the thinnest patients, lesion extension into paraspinal muscles may manifest as increased procedure-related pain. As noted above, placing a grounding pad too close to neurotomy site can increase the risk of skin burns, especially with aggressive lesioning techniques. Strategies to reduce the potential for skin burns during RFA have previously been published and include the use of a large electrical dispersive pad constructed with conductive metal and adhesive polymer gel, positioning the grounding pad with the longest side facing the RF electrode, and for high-risk procedures, consideration of the use of dual grounding pads.[298]

Recommendations

We recommend checking all equipment to ensure that it is properly functioning, and positioning monopolar RF grounding pads in an optimal location and orientation. Applying a large, properly positioned grounding pad on a lower extremity that is dry, clean shaven and devoid of scars or tattoos may minimize the risk of tissue burns; grade B recommendation, moderate-to-high level of certainty.

Impact of RFA on spinal instrumentation in proximity of the procedure

Cadaver studies have shown that anterior lumbar interbody spinal fixation is associated with less facet joint capsular strain at the level of fixation plate.[299] Previous spine surgery is also associated with a higher false-positive rate of MBB, and a lower success RFA rate.[54 133] It should also be noted that during placement of pedicle screws, many surgeons intentionally or unintentionally also sever the medial branches. Yet, it is not uncommon for patients who have had spine surgery with instrumentation to undergo lumbar facet joint RF denervation at levels adjacent to the operated segments. Concerns have been expressed that the use of RFA in patients with existing posterior spinal instrumentation can cause thermal injury to surrounding structures through heating of the hardware.[300 301] However, an observational study of 44 lumbar facet joint RFA procedures in patients with posterior spinal instrumentation did not find any evidence of superficial or deep burns, denervation of the lateral branches or ventral rami, or coagulation of blood vessels.[302]

Recommendations

Multiplanar fluoroscopic imaging-guided RFA technique should be used to ensure that the RF cannula is not in contact with the pedicle screw to avoid thermal injury to tissues surrounding implanted spinal hardware; grade C recommendation, low level of certainty.

QUESTION 16: SHOULD THERE BE DIFFERENT STANDARDS IN SELECTING PATIENTS FOR RADIOFREQUENCY ABLATION IN CLINICAL TRIALS AND CLINICAL PRACTICE?

Key concepts of clinical trial design and disparities in interpretation

Clinical trials are the reference standard to determine the efficacy and effectiveness of novel therapeutics to treat pain. Early phase clinical trials employ strict selection criteria in order to reduce variables that may affect outcomes, and maximize the chance of establishing efficacy. As the therapy moves through the different phases of development, selection criteria are loosened in order to evaluate outcomes in 'real-world' patient populations that better reflect effectiveness. Trying to estimate real-world effectiveness based on rigorously performed efficacy studies is challenging, as increasing exclusiveness undermines generalizability.[303] It is difficult to determine where diagnostic facet blocks and RFA fall on this continuum since there is abundant (yet often conflicting) literature evaluating nearly every aspect of the treatment, as discussed in this review. Therefore, some variables may require more stringent selection criteria to evaluate in clinical trials while others may warrant more liberal criteria that aim to maximize generalizability.[36]

A key concept of clinical trials is that methodology should be contingent on the question being answered (eg, animal studies to determine safety, dosing or treatment parameters; phase III to determine efficacy).[304] Consequently, the design of facet joint studies, including selection criteria, should be tailored to the study's purpose. Studies generally seek to extend our knowledge in a given area (ie, they do not seek to re-test or re-litigate established facts), but a gray area of contention in the interventional pain treatment theater is that there is disagreement on what is established. For example, whereas most interventional physicians agree on the efficacy of facet joint RFA, there is no such consensus in the general medical community. This can lead to differences in interpretation of the extant interventional literature, and for pain physicians to eschew performing pure efficacy studies later in a procedure's lifespan, with that gap being filled by non-interventionalists who are not as attuned to nuances that could improve treatment outcomes. This is highlighted in a review on epidural steroid injections that found that both clinical trials and evidence-based reviews led by physicians who perform the procedure are much more likely to yield positive conclusions than those conducted by non-interventionalists.[305] There is widespread agreement on designing studies to optimize the likelihood of answering the question being asked, and that studies designed for one purpose should not be used to draw conclusions on others (ie, comparative-effectiveness studies with liberal selection criteria should not be used to assess efficacy).[24 25 27]

It is important to recognize that what may be best for an individual person and justifiable in a clinical trial may not be in the best interest of society, or even for an individual practitioner. For example, interventions that are incredibly costly and

time-consuming, but provide only a marginal increase in efficacy may be not be cost-effective on a macrolevel. However, the conduct of early phase clinical trials does not usually reflect clinical practice. Inclusion and exclusion criteria tend to be longer and more rigorous in clinical trials, and the additional costs incurred by being more selective in enrollment and meticulous in performance often pale in comparison to the overall cost of product or drug development.

Patient selection

Similar to all treatments, patient selection for diagnostic facet blocks plays a critical role in determining the likelihood of a positive outcome. There is consensus that failure of at least 3 months of conservative therapy is a reasonable threshold that should be implemented in both clinical trials and practice, although practice guidelines could allow flexibility in cases of extenuating circumstances. The cut-off for clinical trials is similar to what was advocated by an international panel of experts for epidural steroid injection studies, and is predicated on the observation that the natural prognosis is favorable for back pain in individuals with acute pain, even without treatment.[306] There is scant evidence supporting specific physical examination signs or imaging to diagnose facetogenic pain or predict treatment outcomes, so selection should be adapted according to the specific question being addressed.

Patient selection in clinical trials designed to determine efficacy must employ stringent selection criteria to eliminate likely non-responders (eg, individuals with depression, those on high doses of opioids), ensure that participants have the index condition being studied (ie, reduce false-positive rates for MBB), and maximize the chances for technical success even when doing so may not be cost-effective (ie, performing sensory stimulation, creating multiple lesions, utilizing relatively expensive systems that enhance lesion size). However, practitioners on the frontlines treating pain often have different goals. For example, although patients who are depressed and sleep poorly, or are on temporary disability or opioids because of back pain, may not be candidates for a clinical trial aimed at determining efficacy, the upside of treatment in these patients is substantial.

Technique for diagnostic facet block

The goal of the diagnostic block is for the LA to be delivered to the target without extraneous flow to non-targeted structures. There is little controversy over the volume of the injectate, as low volumes have been shown to enhance specificity for MBB and positive predictive value for RF procedures.[98 99 172] The use of contrast, and its ability to detect spread patterns for a less viscous LA solution, is more controversial. For epidural injections, the results are mixed regarding the correlation between the spread of contrast dye, and the spread of LA and sensory blockade.[307 308] The incidence of vascular uptake may be high enough to affect outcomes in small clinical trials that aim to determine efficacy (false-negative blocks) and therefore low volumes (<0.3 mL) of contrast are recommended. However, the injection of contrast, especially gadolinium in those with allergies to iodinated contrast, is not without risk.[309 310] Since the anticipated effect will be much smaller on larger pragmatic trials and in individual patients, its use may not be necessary in all circumstances (ie, the risks and costs may exceed benefits). The use of fluoroscopy is the reference standard for MBBs in both clinical trials and practice, as correct needle position is integral for validity and is unlikely without direct visualization. However, we recommend using CT guidance for IA injections in clinical trials due to the high failure rate of IA injections with fluoroscopy.[18] Sedation has been shown to result in high false-positive rates for diagnostic spinal injections,[160] and individuals who require sedation for MBB should be excluded from clinical trials.

Patient-reported outcomes for diagnostic MBB

The cut-off for designating an MBB as positive is one of the most controversial areas in pain medicine. The studies demonstrating no difference in the predictive value of ≥50% to <80% pain reduction vs ≥80% pain reduction are of higher quality than studies that reported a higher predictive value for an ≥80% cut-off, including the only prospective study to examine this question[6]; hence we recommend using ≥50% for clinical trials, with planned subgroup analyses stratified by per cent pain relief. Given the significant false-positive rate of uncontrolled MBB, it is advantageous that multiple blocks, preferably placebo-controlled, be used to enhance diagnostic accuracy in clinical trials whose aim is to determine efficacy.[209]

Technique for RFA

The goal of RFA is to interrupt as much of the innervation to the facet joint as possible. This is achieved by aligning the exposed needle tip as close to the target innervation and creating as large a lesion as possible, while minimizing damage to non-targeted tissues. The workgroup agrees that visualizing the anatomic location of the needle tip is the most important step. Motor stimulation should be used for safety and can provide confirmation of correct placement by the elicitation of spinal muscle contractions, but may be difficult to discern in patients with obesity, at lower lumbar levels, and in individuals with muscle atrophy. Similarly, sensory stimulation can provide assurance of proximity to the targeted nerve(s), but may be difficult to distinguish from local tissue stimulation, is affected by multiple other factors and was not shown to correlate with RFA outcomes in a prospective study.[268] Therefore, the use of sensory stimulation is not always necessary in clinical practice, but should be used in clinical trials in the absence of an aggressive lesion strategy. The workgroup agrees that larger lesions are relatively easy to effect and may increase the chance of a successful outcome; for this reason, the standards should not differ between clinical trials and practice (use of large-gauge electrodes, temperature ≥80°C, longer lesion times to reduce lesion variability).

Recommendations

This committee interprets the literature to date as demonstrating that lumbar medial branch RFA is efficacious for those patients selected through rigorous methods. Therefore, by relaxing these stringent criteria and performing planned subgroup analyses stratified by percent pain relief, we can further clarify expected outcomes. Studies with the objective of proving efficacy should use the most rigorous selection criteria possible, which may entail multiple blocks with cut-off thresholds exceeding 50% pain relief.

We believe that employing different standards for clinical practice and clinical trials, particularly those that purport to show efficacy, is reasonable (table 11). These differences reflect the different goals for investigators, patients and physicians. Specific areas in which criteria may differ include patient selection (with clinical practice erring on the side of enhanced access to care) for facet blocks and RFA. For RF technique, strategies to maximize lesion size that carry minimal additional risks and costs should ideally be similar between clinical trials and practice; grade A evidence, moderate level of certainty.

Table 11 Guidelines for clinical trials vs clinical practice

Factor	Clinical trial	Clinical practice
Patient selection		
Failure of conservative treatment	At least 3 months	Preferably 3 months, but may be less in certain circumstances (eg, incapacitating pain with strong suspicion of facetogenic origin, competitive athlete, military deployment)
Physical examination	No recommendation	No recommendation
Diagnostic imaging	No recommendation	No recommendation
Facet block technique		
Injectate volume:		
Medial branch block	≤0.5 mL	≤0.5 mL
Intra-articular block	<1.5 mL	<1.5 mL
Imaging:		
Medial branch block	Fluoroscopy	Fluoroscopy
Intra-articular block	CT	Fluoroscopy or CT
Contrast	0.1–0.3 mL	With or without contrast
Sedation	None	Not routinely
Patient-reported outcomes		
Pain relief cut-off	≥50%, consider subgroup analysis for higher thresholds in efficacy studies	≥50%, with lower cut-offs considered in certain circumstances (eg, other metrics of improvement achieved)
Multiple blocks	Strongly consider for efficacy studies	Not routinely
Repeat diagnostic MBB for repeat RFA	No	No
RFA techniqueRFA technique		
Stimulation	Motor necessary; sensory recommended in the absence of multiple lesions	Motor strongly recommended; sensory at discretion of practitioner
Needle size	Large (preferably at least 18-gauge)	Large
Temperature	80°C–90°C	80°C–90°C
Duration	Preferably at least 2 min	At least 1.5 min
Multiple lesions and/ or other techniques to increase lesion size	Necessary in the absence of clear-cut stimulation benchmarks	Depends on circumstances

MBB, medial branch block; RFA, radiofrequency ablation.

QUESTION 17: IN WHICH PATIENTS SHOULD REPEAT RADIOFREQUENCY ABLATION BE CONSIDERED, AND WHAT IS THE LIKELIHOOD FOR SUCCESS? DO REPEAT DIAGNOSTIC BLOCKS NEED TO BE REPEATED?

Rationale for repeating RFA and likelihood of success

Pain relief after RFA of the facet joint nerves is durable compared with steroid injections, but still time-limited.[18 23 311–313] As a result, in current clinical practice RFA is commonly repeated on recurrence of pain. Educating patients about the possibility of temporary relief and the potential for repeated treatment is a part of the informed consent process for this treatment, and information about the likelihood of success with repeated treatment is central to this discussion. A 2012 systematic review by Smuck *et al* examined the literature on the success of repeat lumbar RFA.[314] From seven qualifying studies that provided data on repeat RF outcomes, the unweighted average success rate of repeat RFA was approximately 80% in patients who experienced a good outcome from the first RFA procedure, typically defined as at least 50% relief of pain at 3 months. The 3-month cut-off for designating an RFA procedure as a success is based on a study by Cohen *et al* in which 15 patients and 5 pain physicians were surveyed in preparation for a randomized trial of RF outcomes.[7] These repeat RFA results differed somewhat between lumbar and cervical RFA studies, with a 59% success rate based on the two qualifying lumbar studies (n=29) and an 88% success rate based on the five qualifying cervical studies (n=114). The average duration of pain relief was also similar following repeat RFA compared with the initial RFA response (10 months). Alternatively, when response to the first RFA did not meet the 3-month cut-off for a positive outcome, repeat RFA was less successful (38% based on data from the five cervical spine studies, lumbar data not available).

Additional studies that were not included in the above-mentioned systematic review, because of publication date or not meeting selection criteria, shed further light on the effectiveness of repeat RFA. A prospective cohort study by Rambaransingh *et al*[315] examined outcomes in patients with successful response to an initial lumbar medial branch RFA who underwent a second (n=58) and third (n=29) RFA treatment, demonstrating the repeatability of treatment success. Clinically meaningful mean improvements in pain and disability were observed after each of the RFA treatments, and without statistical differences in treatment duration or effect size between the first, second and third RFAs (mean pain score reductions of 3.2, 3.3 and 4.1, respectively). Son *et al* performed a retrospective analysis in 60 patients who received one or two repeat lumbar medial branch RFAs after an earlier successful treatment.[316] The first and second repeat RFAs were successful in 91% and 80% of cases, respectively, with no statistical differences in the duration of relief (mean duration 10.9 and 10.2 months after the initial and repeat procedures, respectively). Similar results were reported by Kim *et al* (95% success rate with repeat RFA) in a retrospective cohort study evaluating 56 patients with facet joint pain following lumbar microdiscectomy who were treated with a repeat RFA when pain returned following a previously successful RFA.[317] In this study, the proportion of patients with >50% pain relief was 91% for the second procedure (mean duration of relief 10.2 months) and 80% after the third procedure (mean duration 9.8 months). More recently, MacVicar *et al*[216] described outcomes from a prospective consecutive cohort (n=106) treated with lumbar RFA whereby 56% experienced complete relief of pain, full restoration of function and no need for analgesic medications or other back pain treatments for a median duration of 15 months. Fifty-six per cent of these patients received repeat RFA (between one and five treatments) with all experiencing similar robust treatment effects and durations of benefit (median 13 months) following the repeat procedures.

In summary, there is good evidence to support repeat medial branch RFA, with a high likelihood of success (at least 80%) in patients who experience at least 50% pain relief for a period of 3 months or longer following their initial RFA treatment. According to multiple studies, improvements in pain and function and duration of benefits are similar between repeat and initial lumbar facet RFA treatments.

Rationale for durability and repeatability of RFA

The mechanisms that underlie the durability of RFA outcomes remain under debate. The electrode temperature and duration of the RF delivery are intentionally chosen to cause axonal destruction and Wallerian degeneration of the medial branch nerve, but are not sufficient to injure the collagenous tissues that form the nerve sheath (ie, third-degree peripheral nerve injury based on the Sunderland nerve injury classification).[248 318] As a result, the proximal surviving axons can regenerate via the intact neural tube and re-establish facet joint innervation and pain perception. This is the most likely reason that some patients experience return of pain and need to repeat the procedure. What is

less clear is the reason for the observed durability of RFA treatment effects, lasting 10 months or more based on a systematic review.[314] Injured axons regenerate at a rate of 1–2 mm/day, although the rate depends on many factors and can vary significantly from individual to individual.[319] Since the length of nerve from the axonal lesion to the lumbar facet joint is approximately 30–40 mm, reinnervation could occur within 3–6 weeks. Regeneration is the primary form of nerve repair when >90% of the axons are injured. In partial nerve injuries when only 20%–30% of the axons are affected, collateral sprouting from preserved axons can contribute to reinnervation.[248] Some researchers have suggested that the prolonged pain relief observed from RFA results from the heat lesioning slowing nerve regeneration, or reinnervation.[248 320 321]

Rationale for not repeating prognostic blocks before repeat RFA

Despite the known durability of RFA treatment outcomes, a substantial number of patients who respond to RFA will experience a return of pain. The pathophysiological mechanisms behind this are described in the preceding paragraph. Each study included in the systematic review by Smuck *et al*,[314] and all of the individual studies discussed previously specified that a positive response to prognostic blocks was the criterion used to select patients for the initial RFA treatment. None comment about the role of repeat prognostic blocks in the decisions to repeat RFA, suggesting that repeat prognostic blocks did not play a role in the decision to repeat the denervation procedures, and thus are not necessary.

From a practical standpoint, when pain returns it may not be clear that it stems from the previous source. This can be particularly challenging when relief from the prior RFA lasts considerably longer than expected, as some patients have reported benefit lasting >5 years from a single RF treatment.[216] As a result, physicians sometimes choose to repeat the prognostic blocks before repeating RFA. This may be more useful when a patient's description of the index pain has changed, or if the patient or physician is uncertain if the current pain is the same or similar to previous pain. To our knowledge, no studies provide data to help guide when repeat prognostic blocks are needed prior to repeating a previously successful RFA.

Period of waiting

Studies have demonstrated that patients with shorter duration of pain respond better to an initial RFA of the lumbar medial branches for facet joint pain,[54] and sacral lateral branches for SI joint pain,[200] than those with a longer duration. Whereas there are no data evaluating the effect that the duration of pain following a recurrence has on repeat RFA outcomes, based on this information, the relatively high success rate for repeat lumbar medial branch RFA, and the disability associated with lumbar facetogenic pain, one might reasonably surmise that repeat RFA should be performed shortly after symptoms recur. However, repeating RFA may have irreversible consequences if performed too early. Denervation of the paraspinal musculature including the multifidus muscle has been demonstrated to last over 12 months in some patients.[147] When a muscle is denervated, it proceeds through several well-documented stages that are measured in months in most laboratory animals, but can take several years to denouement in humans. Immediately after denervation, immediate loss of function and microscopic muscle atrophy ensue. The second stage is characterized by increasingly severe muscle atrophy, which includes the loss of most sarcomeric organization. The final phase consists of irreversible, interstitial fibrosis, whereby muscle tissue is replaced by adipocytes.[322 323] Since there are reports of patients getting multiple repeat RFA procedures over a period of years, and motor units may be more susceptible to irrevocable long-term sequelae than nociceptors, performing repeat RFA multiple times preemptively (ie, before pain recurs) has the potential to result in irreversible damage to the paraspinal musculature.

Recommendations

The committee recommends repeating lumbar medial branch RFA on recurrence of pain in patients who experience a minimum of 3 months of improvement (and preferably 6 months improvement for multiple procedures) following a previous RFA. Given the drop-off in success rates reported in some studies and the mean duration of benefit, we recommend repeating the procedure no more than two times per year; grade B recommendation, moderate level of certainty.

The committee does not recommend routine use of repeat prognostic blocks before repeat lumbar medial branch RFA in patients who experience a recurrence of their baseline pain in a physiological time frame, but we recognize that they may be useful when it is unclear if the current pain is the same or similar to the pain experienced before the previous RFA; grade C recommendation, low level of certainty.

DISCUSSION

Perspective and bias

Facet-related procedures have become a deep-seated source of controversy in the pain medicine and general medical communities. An analysis of clinical trials and evidence-based reviews reveals that those performed by non-interventionalists are most likely to generate negative findings[85 90 324] compared with those performed by individuals who perform facet blocks and RFA,[81 217 325] which is similar to what has been found for epidural steroid injections.[305 326] In the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) guidelines on unique considerations for interventional studies, the authors attributed this discrepancy to better selection and technique for interventionalists, differences in interpretation that reflect differences in background and understanding, and bias on both sides of the debate (table 12).[36]

Balancing access to care against maximizing success rates

A major point of contention in developing our guidelines revolved around disparities in the perceived objectives. Whereas it was charged from the outset that these guidelines should be designed to inform care in clinical practice, creating a balance between maximizing access to care for a minimally invasive procedure with a low complication rate for which there are no reliable evidence-based treatment alternatives (ie, formulating guidelines with liberal selection criteria to minimize false-negative results) and devising more stringent criteria which would promote higher RFA success rates (ie, minimizing false-positive results) proved to be a formidable task. In the end, we opted to err on the side of greater access to care, relying on education, peer-review and regulatory bodies to limit and prevent overuse.

Overuse is not limited to facet interventions, as studies have shown significant geographic variations in spine surgery and epidural steroid injection rates, with minimal correlation between the number of procedures performed and disability rates.[327–329] Overuse may be an inevitable byproduct of a fee-for-service payment system, although the incentives for high

Table 12 Summary of recommendations

Topic	Recommendation/Findings	Level of evidence and certainty
Value of history and physical examination to select patients for blocks	There are no examination or historical signs that reliably predict response to lumbar facet blocks. Paraspinal tenderness and radicular symptomatology may be weakly predictive of positive and negative blocks, respectively. The levels targeted should be based on clinical presentation (eg, tenderness, pain patterns, imaging if available).	Grade C, low level of certainty
Correlation between imaging and facet block and RFA outcomes, and whether imaging is necessary before blocks	There is moderate evidence for SPECT before MBB. There is weak evidence for SPECT before IA blocks. There is weak evidence for MRI, CT and scintigraphy before MBB and IA blocks.	Grade C, moderate level of certainty Grade D, low level of certainty Grade D, low level of certainty
Requirement of conservative treatment including physical therapy before facet blocks	Consistent with clinical practice guidelines, we recommend a 3-month trial of different conservative treatments before facet joint interventions.	Grade C, low level of certainty
Necessity of image guidance for lumbar facet blocks and RFA	We recommend CT or preferably fluoroscopy be used for lumbar MBB, although ultrasound may be considered in certain contexts. For IA injections, we recommend CT, although fluoroscopy can be considered in some cases.	Grade C, low level of certainty
	For RFA, we recommend using fluoroscopy.	Grade B, low level of certainty
Diagnostic and prognostic value of facet blocks	IA injections are theoretically more diagnostic than MBB, although they are characterized by a high technical failure rate and poorer predictive value before RFA. Both MBB and IA injections are better than saline injections as prognostic tools before RFA.	Grade B, low level of certainty
MBB vs IA injections before RFA	MBB should be the prognostic injection of choice before RFA. IA injections may be used for both diagnostic and therapeutic purposes in some individuals (eg, young people with inflammatory pain, people at risk of RFA complications).	Grade C, moderate level of certainty.
Effect of sedation on diagnostic and prognostic utility	Consistent with guidelines, sedation should not be routinely used in the absence of individual indications.	Grade B, low-to-moderate level of certainty
Ideal volume for facet blocks	Lumbar MBB should be performed with a volume ≤0.5 mL to prevent spread to adjacent structures, and IA injections should be done with a volume <1.5 mL to prevent aberrant spread and capsular rupture.	Grade C, low level of certainty
Therapeutic benefit from MBB and IA injections	We recommend against the routine use of both therapeutic MBB and IA injections, although we acknowledge there may be some contexts in which these can be useful (eg, prolonged relief from prognostic blocks, contraindications to RFA).	Grade D, moderate level of certainty
Cut-off for designating a prognostic block as positive and use of non-pain score outcome measures	We recommend that ≥50% pain relief be used as the threshold for designating a prognostic block as positive, but recognize that using higher cut-off values may result in higher RFA success rates. Secondary outcomes such as activity levels may also be considered when deciding whether to proceed with RFA.	Grade B, moderate level of certainty
Number of prognostic blocks performed before RFA	We recommend a single block. Although using multiple blocks may improve RFA success rates, it will also result in patients who might benefit from RFA being denied treatment.	Grade C, low-to-moderate level of certainty
Evidence for large RF lesions	There is indirect evidence, and limited direct evidence, that techniques that result in larger lesions (eg, larger electrodes, higher temperatures, longer heating times, proper electrode orientation, fluid modulation) improve outcomes.	Grade C, low level of certainty that larger lesions increase the chance of capturing nerves. Grade I, low level of certainty that larger lesions increase duration of pain relief.
Electrode orientation	We recommend positioning the electrode in an orientation near-parallel to the nerve.	Grade B, low level of certainty
Use of sensory and motor stimulation before RFA	Sensory stimulation should be used when single lesions are anticipated. When multiple lesions are planned, the evidence for sensory stimulation is inconclusive. Motor stimulation may be beneficial for safety and effectiveness purposes.	Grade C, low level of certainty Grade I, moderate level of certainty Grade B, low level of certainty
Mitigating complications	Intravascular uptake can adversely affect the validity of MBB and we recommend aspiration and real-time contrast injection.	Grade C, low levelof certainty
	Anticoagulation medications should be continued for facet blocks and RFA, and cases that might warrant discontinuation should be discussed with relevant healthcare providers.	Grade B, moderate level of certainty
	Injection of steroid after RFA may prevent neuritis.	Grade C, low levelof certainty
	Confirming electrode placement in multiple views andusing sensorimotor testing may reduce the risk of nerveroot injury.	Grade B, low levelof certainty
	RFA can result in paraspinal muscle degeneration andpossibly disc degeneration, though the clinical relevanceof this is unclear. We recommend a discussion of thispossibility with patients, and consideration of physicaltherapy before and after RFA to reduce the risk.	Grade C, low levelof certainty
	Interference with implanted electrical devices can occur,and physicians should consult with relevant healthcareteams regarding recommendations (eg, programmingpacemakers to asynchronous mode, turning offneurostimulators). Bipolar modes may be safer thanmonopolar, and grounding pads should be placed awayfrom implanted cardiac devices, but not too close to theneurotomy site (risk of tissue burn). Avoid excessivesedation.	Grade C, low levelof certainty
	Burns may occur from equipment malfunction or lesionextension to the skin (less likely). Checking equipment,and properly positioning the grounding on a dry, cleanshaven lower extremity devoid of scars may minimize thisrisk.	Grade B,moderate-to-highlevel of certainty
	Spine surgery is associated with lower RFA success rates,and physicians should check placement of RF probes inmultiple fluoroscopic views and avoid contact withhardware to prevent thermal injury.	Grade C, low levelof certainty
Difference in standards between clinical trials and clinical practice	Providers involved in clinical trials and clinical practice may have different goals that warrant different selection and performance criteria. Areas that might warrant discrepancies include the use of contrast during MBB, number of blocks performed, prognostic block cut-off for identifying an RFA candidate and use of sensorimotor stimulation.	Grade A, moderate level of certainty
Repeating RFA	We recommend repeating RFA in individuals who obtained at least 3 (and preferably 6) months of relief, up to two times per year. The success rate for repeat RFA decreases for successive procedures but remains above 50%.	Grade B, moderate level of certainty
	Repeating prognostic blocks is not routinely necessary in patients who experience a recurrence of their baseline pain in a physiological timeframe.	Grade C, low level of certainty

online supplementary figure 1
IA, intra-articular; LA, local anesthetic; MBB, medial branch block; RF, radiofrequency; RFA, radiofrequency ablation; SPECT, single photon emission computed tomography.

procedure utilization are multifarious. For example, a depressed, overweight patient with marital problems and sleep abnormalities who is on disability and opioids for back pain may be a great candidate for facet interventions because of the huge upside of the minimally invasive treatment, but from a payer's perspective the same patient may be a poor candidate because they are statistically unlikely to benefit.[305 330–332] Increases in utilization alter the risk-to-benefit ratio for procedures, as laxer selection tends to reduce the likelihood of benefit. This is complicated by the fact that an insurer is unlikely to reap the financial benefits for a patient who returns to work, or staves off an impending divorce.

For pain medicine procedures, utilization is not uniformly distributed. One study found the top 10% of pain medicine proceduralists perform 36.6% of all spinal procedures, which is ninefold higher than the lowest 10%.[333]

Recommendations in the absence of high-quality evidence

The requirements for FDA approval of devices differ from those of medications in that they are less rigorous. This fact, along with the inherent challenges in performing randomized trials for procedures (eg, recruitment, blinding, funding for expensive

procedures), has led to a relative paucity of evidence. However, as Altman and Bland so eloquently stated nearly 25 years ago, the absence of evidence does not equate to the evidence of absence.[334]

The United States Preventive Services Task Force guidelines have previously been adapted for pain medicine procedures,[30–33] and are flexible enough to allow for recommendations based on evidence outside the realm of traditional clinical trials. This holds particularly true for fundamental concepts (ie, the use of imaging to perform a procedure that nearly everyone acknowledges requires visualization), technical aspects (ie, electrode orientation) and reducing complications. Regarding technical aspects, if one operates under the premise that RFA exerts its beneficial effects from interrupting the neural pathway from the facet joints, and that failure to capture the neural target is a potential source of treatment failure, then it becomes axiomatic that strategies to enhance lesion size have the potential to reduce technical failures. This is the same argument that was used for decades to justify selective nerve blocks and electrodiagnostic testing before decompression surgery, which only later were shown in clinical trials to be predictive for outcome.[171 335] For complications, it is nearly impossible to power a randomized trial to detect rare events such as serious complications, so that other tools such as case-control studies and registries must be used to draw conclusions.[336] As an example, in the multispecialty working group guidelines on epidural steroid injections, the authors unanimously concluded that imaging be used for cervical injections and that only non-particulate steroids be administered for cervical transforaminal injections, despite the absence of any randomized trials demonstrating safety.[337] In fact, concluding safety based on non-significant differences in adverse events between groups in randomized trials is considered to be evidence of 'spin'.[338]

Guideline limitations

Unlike standards which generally come from an undisputed authority and are limited in application, guidelines tend to be more flexible, providing recommendations on areas of uncertainty. However, what may be an appropriate treatment approach for one patient may not work for another. An example might be proceeding straight to RFA without a diagnostic block in an elderly person with pronounced facet joint degeneration on imaging, who is on anticoagulants for a high-risk condition, and is from out of state or country.

These guidelines should thus serve as a framework to guide care, not as immutable standards. Similar to the US Centers for Disease Control and Prevention opioid guidelines,[339] which have been criticized for being taken out of context by some insurance carriers and limiting access to care, payers should consider context, unique clinical considerations and provider and patient input, rather than mandating inflexible application.[340 341]

A second limitation was the high number of participants in our workgroup representing multiple countries and professional organizations, which is more than what is typically recommended to achieve consensus, but was necessary to ensure the participation of multiple stakeholder organizations. This led to the creation of subcommittees for individual questions, which were sent to the entire committee after editing by the Committee Chair. The use of small subcommittees to develop recommendations can result in an inability to come up with the best answer, while the large number of participants in the main committee can lead to inefficiency and failure to consider everyone's opinion.

Third, we did not grade the studies we included, as current grading scales focus on methodological shortcomings of clinical trials, but fail to consider the more important aspects of selection and technique.[342] For grading scales involving non-randomized studies, there is no consensus on which instruments are the most valid, and the same limitations apply.[343] Grading studies also requires considerable time and involves reconciling discrepancies. A major downside of guidelines that have taken years to assemble is that they are often out-of-date on some subjects by the time they are published.

Fourth, recommendations by nature are influenced by the opinions and clinical experience of the group, which in our case contained only academically accomplished interventional pain physicians. This was done because the questions we considered were mostly technical, rather than overarching ones such as effectiveness. It is therefore possible that including more private practitioners, non-pain physicians and even patients may have led to different conclusions.

Finally, our guidelines were designed to prioritize patients' needs, but patients' needs may not be the only consideration for policy recommendations. Practices that are suboptimal from an individual patient's perspective (or even the entire population of lumbar facet joint pain sufferers) may be utilitarian from society's standpoint in order to prevent overuse, preserve confidence from payers and regulators, and control costs. An example of this might be requiring a cut-off threshold for designating a prognostic block as positive, rather than leaving it up to patients as to whether they achieved enough benefit to proceed with RFA.

Literature gaps and areas for future research

We chose 17 questions to address in these guidelines, but this list is by no means exhaustive. In many cases, the answers to the questions we addressed will be controversial precisely because there are gaps in the literature. Areas of controversy include all aspects of lumbar facet joint arthropathy, such as the value of history, physical examination and imaging to select block candidates, how to perform and interpret diagnostic injections, technical aspects of neuroablation and how to synthesize the existing evidence on RFA. Table 13 outlines some areas ripe for future research.

CONSENSUS

The presubmission version of these guidelines was sent to participating organizations on 9 October 2019, and approved by all who voted by 8 November 2019, except for the American Society of Anesthesiologists, who requested a 3-week extension. There was 100% consensus among the committee members (coauthors) for each recommendation. Nine of the 13 organizations approved every recommendation, with one (SIS) dissenting on questions 10 (cut-off for designating a facet block as positive) and 11 (number of blocks that should be performed before RF ablation). Specifically, SIS believes the cut-off for a positive block should be 80% rather than 50%, and that two positive blocks should be routinely required in the absence of mitigating circumstances. The American Pain Society disbanded during the development of the guidelines and did not vote. These guidelines were approved en bloc by the American Society of Anesthesiologists' Administrative Council and Committee on Pain Medicine, but were not voted on by their Board of Directors or House of Delegates. The Departments of Defense and Veteran Affairs did not vote on the document per internal regulations (ie, these guidelines were not solicited and funded by those organizations),

Table 13 Major and minor areas for future research

Minor areas	Major areas
Refine the means to identify target nerves (eg, real-time electromyography, more reliable stimulation technique).	Develop safer and more efficient means for medial branch RFA (eg, laser therapy, high-intensity focused ultrasound).
Determine the best way to prevent major and minor complications (eg, nerve injury, neuritis).	Identify ways to prolong benefit from RFA (eg, by injecting factors that inhibit nerve regeneration).
Identify non-ablative treatments for lumbar facet arthropathy (eg, tools to identify responders to IA steroids or to prolong benefit from steroids, pharmacotherapy, integrative treatments).	Develop tools (eg, imaging, biomarkers, questionnaires) to identify painful facet joints.
Perform comparative-effectiveness studies to determine the optimal selection criteria and technique.	Develop predictive modeling tools (ie, the use of history, examination findings, psychosocial metrics and imaging) to improve prognosis and better foretell outcomes.
Enhance precision of diagnostic blocks (eg, identify optimal injection volumes, number and types of blocks, amount of LA, needle location, needle size).	Investigate role of regenerative therapies in reducing or reversing pain from arthritic facet joints.

IA, intra-articular; LA, local anesthetic; RFA, radiofrequency ablation

but sent representatives (the US Army Pain Medicine Consultant to the Surgeon General and the Director of Interventional Pain Management) to participate in guideline development, and they concurred with all recommendations.

CONCLUSIONS

In summary, these multiorganizational facet intervention guidelines are meant to serve as a blueprint to guide care in an era characterized by increasingly polarized views, where there is often a lack of communication between parties with different opinions. These guidelines should not be misconstrued as unalterable standards, nor can they account for every possible variation in presentation or treatment circumstance. Similar to all facets of medicine, the decision about when to implement treatment, how to interpret treatment outcomes and how best to weigh risks and benefits based on unique patient considerations should be made on an individualized basis (ie, personalized medicine) after sufficient discussion with the patient. As has been alluded to previously, evidence-based pain medicine should include consideration of the best-available research, and take into account clinical experience and expertise, as well as patient values and preferences.[344]

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Facet Joint Interventions

DEFINING APPROPRIATE COVERAGE POSITIONS

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Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 11/1/2015; information and data available after 11/1/2015 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology

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

NASS Coverage Policy Methodology

Background Information

Published, peer-reviewed studies have established prevalence estimates for cervical and lumbar facet joint pain in chronic neck (CNP) and low back pain (CLBP) subjects, respectively. Lumbar facet joint pain occurs in 15-32% of CLBP patients[1-3] with patients over age 55 years most commonly affected.[1,2] In the lumbar spine, L5-S1 is the level most commonly responsible for pain followed by L4-5.[1,2,4,5] Cervical facet joint pain occurs in 55-69% of CNP patients[6-10] and increases after whiplash injuries.[6] In the cervical spine, C2-3 has been found to be the level most commonly responsible for upper neck and headache pain while low neck pain has been found to associated more often with C5-6.[6] In most cases, a single joint is the source of symptoms.[7] The prevalence of thoracic facet involvement in chronic thoracic pain has been estimated to be as high as 48%.[11]

Facet Joint Interventions: Diagnostic and Therapeutic

Scope and Clinical Indications

Injections involving the zygapophysial joints (Z-joints) can be indicated for diagnostic or therapeutic purposes. Therapeutic injections typically involve administration of corticosteroids, with or without local anesthetics, while diagnostic injections use anesthetic alone. This document will cover the diagnostic uses and therapeutic uses of intraarticular Z-joint injections and of diagnostic medial branch blocks.

The pain referral patterns of the cervical Z-joints are described and can include pain in the neck, and/or the head, and/or the periscapular and shoulder region.[12] The pain referral patterns of the lumbar Z-joints are similarly described and can include pain in the back, gluteal area and leg.[13,14] For patients with such pain, the procedures covered in this report may be considered when ALL of the following criteria are met:

1. The patient's pain is severe enough to cause some degree of functional deficit.
2. Failure of at least 4 weeks of noninvasive care (see below*).
3. There is no other significant pathology that could explain the source of the patient's pain, such as fracture, tumor, infection or significant extraspinal lesion.
4. Pain is predominantly axial, within the locations described above, and not associated with radiculopathy or myelopathy.
5. Clinical assessment implicates the Z-joint as the putative source of pain.

* It is known that the majority of back and neck pain will improve over 4 weeks. It is therefore reasonable to recommend failure of 4 weeks of nonsurgical, noninvasive care. Appropriate nonsurgical, noninjection treatments should be considered along with a rationale for interventional treatment. Exceptions to waiting 4 weeks can exist but should be carefully documented and should be reviewed on a case-by-case basis. These include but are not limited to:

a. At least moderate pain with significant functional loss at work and/or home.
b. Severe pain unresponsive to outpatient medical management.

c. Inability to tolerate nonsurgical, noninjection care due to coexisting medical condition(s) (eg, cardiac disease).
d. Prior successful injections for the same condition.
e. The presence of a facet synovial cyst causing nerve root compression with moderate-severe radicular pain and associated functional limitations.

Of note, any and all cervical spine injections should be performed with some form of image guidance (eg, fluoroscopy or CT).

Intervention 1: Diagnostic Medial Branch Blocks

Zygapophysial joint medial branch blocks (MBBs) are a validated means to diagnose Z-joint related pain[15], which can include pain in the back, neck, and/or the head and/or the periscapular and shoulder region. Notably, this also includes the third occipital nerve since it innervates the C2-C3 Z-joint. Medial branch blocks, properly conducted, will anesthetize the target Z-joint(s), including the intraarticular surfaces, the joint capsule and the adjacent tissues including the paravertebral muscle supplied by the medial branch of the cervical dorsal ramus. The primary utility of MBBs is to determine the suitability of the patient for a radiofrequency neurotomy of painful segmental levels identified by the diagnostic MBBs, in order to achieve long-term management of the patient's pain.

When diagnostic MBBs are performed, the following criteria apply:

1. Dual blocks, performed in the same location(s) on 2 separate occasions, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single diagnostic anesthetic injections in the spine.
2. A second confirmatory injection is indicated only if the first injections produces ≥80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed. This confirmatory block confirms the tested joint as the source if the index pain is reduced by > 80%.
3. A second injection may also be performed at a different or additional level if the pain is believed to be arising from a different joint (and the pain relief from the initial block was <80%).

Intervention 2: Therapeutic Medial Branch Blocks

Therapeutic MBBs are performed in the same manner as diagnostic MBBs, but the therapeutic blocks are intended to achieve long-term management of the patient's pain.

While MBBs are valid and reliable diagnostic procedures, current evidence does not support their use as a therapeutic intervention. Currently published research shows that the number of therapeutic MBB injections required in a single year (4-5) exceeds the number of therapeutic injections recommended for routine use elsewhere in this report, and no benefits are observed when adding corticosteroids or other potentially therapeutic medications to traditional anesthetic MBBs. Therefore, therapeutic MBBs are not recommended in the treatment of back or neck pain.

Intervention 3: Diagnostic Intraarticular Zygapophysial Joint Injections

Unlike MBBs, intraarticular (IA) Z-joint injections have not be validated as a means to diagnose Z-joint related pain and should generally not be used in lieu of MBBs for the diagnosis of suspected Z-joint pain. IA anesthetic injections are capable of blocking only the articular joint surfaces and interior joint capsule. There have been no studies that have compared the diagnostic effectiveness of intraarticular Z-joint injections versus MBBs.

IA Z-joint blocks should not be used as a diagnostic test unless MBBs cannot be performed due to specific documented anatomic restrictions. For example, in the case of the occipitoatlantal and atlantoaxial joints, there is no medial branch or other innervation available to block reliably, so IA injections are the only means of arriving at a potential diagnosis of pain from these joints.

If diagnostic IA Z-joint injections are performed, the following criteria apply:

1. Dual IA injections are necessary to confirm the diagnose pain due to the unacceptably high false positive rate of single diagnostic injections in the spine.
2. A second confirmatory injection is indicated only if the first injections produces ≥80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed.

Intervention 4: Therapeutic Intraarticular Zygapophysial Joint Injections

There is some evidence in the current medical literature of clinical efficacy of IA Z-joint injection techniques in the treatment of chronic low back pain, chronic neck pain and/or its associated headaches, periscapular and shoulder pain. There are 3 published RCTs along with multiple cohort studies demonstrating short to mid-term relief of pain following intraarticular steroid injections, though when compared with RFA, RFA offers longer term relief in patients with chronic pain.[16-18] Long-term outcomes have not been reported in adequately designed studies. Thus, utility has not been well established in the medical literature. As a result, the use of therapeutic IA Z-joint injections is an empiric practice, related to past experience and extrapolation of the presumed benefits of steroid injections from their use in other synovial joints.

- Therapeutic IA injections should be repeated no more than three times annually and only if the initial injection results in significant pain relief (> 50%) for at least 3 months.

There is a unique subset of patients that suffer from lumbar radicular pain due to facet joint pathology. In these cases, facet synovial cysts may cause nerve root compression or irritation with associated radicular pain similar to other neuro-compressive lesions. A number of interventional treatments for symptomatic Z-joint cysts has been described including intraarticular aspiration,[19-21] injection,[16-18, 20-22] rupture[23, 24] and direct cyst puncture.[25,26] Each of these treatments require direct access into the Z-joint under fluoroscopic or CT guidance. In addition, it is appropriate and indicated to perform a transforaminal epidural steroid injection (one or two level) in combination with the above techniques to treat the associated radiculitis. These are distinct and separate procedures used to treat two separate and distinct but associated pathologies and diagnoses.

For the treatment of Z-joint synovial cysts with Z-joint aspiration/injection/rupture or direct puncture, the following criteria apply:

- The procedure should not be repeated more than two times on the same joint annually and only if the initial procedure results in significant pain relief (> 50%) for at least three months.

Intervention 5: Therapeutic Medial Branch Radiofrequency Neurotomy

Therapeutic medial branch RFN is a validated treatment for Z-joint pain. Long-term follow-up demonstrates that treatment effects are durable and reproducible if symptoms return.[27, 28] Success rates for initial treatment are high when patients are selected based on dual confirmatory diagnostic MBB. If symptoms return, repeat treatment shares an equally high success rate if response to the prior RFN lasted at least three months.[29]

If therapeutic medial branch RFN is performed, the following criteria apply:

1. RFN is offered to patients only if dual diagnostic MBB injections each produce ≥ 80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed.
2. RFN should be performed using a 20-gauge or larger needle with ≥ 10 mm active tip in lumbar spine and at least 5 mm active tip in the cervical spine. Heating must be performed to at least 80 degrees Celsius for 90 seconds in the lumbar and cervical spine.[29-33] Repositioning and multiple lesions may be required to achieve appropriate denervation.
3. The patient should have pain that has been present for at least 3 months despite other treatments.
4. RFN should be performed at the same level no more than twice annually and only if the initial radiofrequency lesion results in significant pain relief (> 50%) for at least 6 months. In those situations, a repeat procedure in that year is appropriate.

Rationale

The proposed policy utilizes an evidence-based approach to care, where such evidence exists. In the absence of strict evidence-based criteria, the policy utilizes the multidisciplinary and non-conflicted experience and expertise of the committee in order to reflect reasonable standard practice indications in the United States.

Image guidance is considered mandatory for successful needle placement for both IA and MBBs. The vast majority of studies have used fluoroscopy during needle placement. Ultrasound is experiencing increasing popularity in the cervical spine due to the proximity of the target structures to the skin and thus the ability to visualize these structures; however, at the time of this publication, the use of ultrasound to perform any of these procedures is considered experimental, and NASS does not recommend coverage at this time. CT

guidance has also been used to direct needle placement, particularly for intraarticular injections.

Medial Branch Blocks

As described in Intervention 1, there are no valid historical physical exam findings, imaging studies or tissue examinations that can identify the cervical facets joints as the source of a patient's neck pain, headaches or shoulder girdle pain. The rationale for using diagnostic cervical MBBs is that pain relief during the anesthetic nerve block provides prima facie evidence that the patient's pain is caused by structures innervated by the target nerves.[34-40] In addition to determining the possible cause of the patient's pain, positive responses to diagnostic MBBs are an indication for a medial branch radiofrequency neurotomy. The effectiveness and long-term durability cervical medial branch radiofrequency neurotomy has been studied by multiple authors and is discussed elsewhere in this coverage document.

Since there is evidence of a significant false positive rate for diagnostic cervical medial branch blocks,[41, 42] dual confirmatory (or "comparative") blocks with local anesthetics of different expected durations of effect, administered on two separate occasions, are recommended to decrease the rate of false positive results. However, the increased specificity afforded by comparative blocks comes at the cost of decreased sensitivity , meaning that the number of false negative patients will increase, meaning some will be disqualified from potentially effective treatment.[35,43]

While the rate of false positives is lower with dual blocks, some have suggested that this practice is neither necessary nor cost effective.[44] However, the study used to make this argument used provocation discography to identify false positives, when provocation discography is controversial specifically for its potential to produce false positive results.[45] Placebo controls have also been advocated to further improve the specificity of MBBs.[46] The decision to use placebo controls is felt by some to depend on whether or not absolute diagnostic certainty was critical, such as in the performance of an initial placebo controlled trial of treatment efficacy, in a medicolegal context or if surgery is contemplated based on the results of the testing.[36] Still, no studies have used cervical IA or medial branch blocks to predict surgical outcomes. Thus, the primary indication for diagnostic cervical MBBs is to determine the suitability of the patient for a radiofrequency neurotomy of the painful segmental level(s) identified by the diagnostic MBBs, in order to achieve long-term management of the patient's pain.

In Intervention 2, the rationale behind therapeutic MBBs is that that compression or inflammation of the medial branch nerve may be responsible for Z-joint related pain or that injections of anesthetic and other potentially therapeutic substances may cause local nerve or central nervous system changes in pain transmission. However, these suggested mechanisms have never been demonstrated empirically.

Prospective randomized studies of therapeutic MBBs compared the standard anesthetic MBBs with blocks combining anesthetics and corticosteroids, showing no differences between groups in terms of pain relief, function, or number of required injection treatments.[47,48] In these studies, patients in each group received an average of 4-5 injections per year for diagnosis and treatment.

Therapeutic cervical medial branch blocks showed short-term relief in an initial small case series published in 1986.[49] Since then, nearly all research on therapeutic MBBs has come from a single center and includes a prospective case series and publications from a randomized controlled trial.[50, 51] The outcomes documented in these studies involve patients who received between 4-5 injections in the first year of the trial. The repeated treatments were performed at various unspecified intervals, without reporting their timing relative to outcomes collection. Thus, it is impossible to determine the true duration of treatment effect. Furthermore, the publications from the randomized trail reveal no additional benefits when other potentially therapeutic medications, such as corticosteroids, are added to traditional anesthetic MBBs. There are no studies that have compared the effectiveness of therapeutic MBBs injections with medial branch radiofrequency neurotomy, a treatment known to provide effective long-term management of cervical Z-joint pain. Only one study has compared therapeutic MBBs to any other treatment, and this was in the lumbar spine. In this prospective, blinded, randomized trial patients were treated with the same combination of corticosteroids and anesthetics with MBBs vs. IA Z-joint injections.[18] Statistically significant and clinically relevant improvements were observed in IA Z-joint injection group relative to the therapeutic MBB group.

Intraarticular Injections

As detailed in Item 3, cervical IA Z-joint injections have not been validated for diagnostic use. Thus, their false positive rate is not known. Lacking validity, they have limited utility in the diagnosis of Z-joint pain.[52] There have been no studies that compare the ef-

fectiveness of IA Z-joint injections vs. MBBs in the cervical spine. The use of diagnostic IA injections is thus reserved for those cases where MBBs are not anatomically possible, as is the case with occipitoatlantal and atlantoaxial joints.

In Item 4, the use of therapeutic IA Z-joint injections is placed into context. Corticosteroid injections for painful joint conditions outside the spine are a common practice, yet evidence is relatively lacking for these therapeutic joint injections – both within and outside the spine. Therefore, policy regarding the recommended indications and frequency of IA Z-joint injections is largely based on limited case series and anecdotes.[53-57] Results of existing studies are conflicting. In controlled trials, benefits relative to other treatments are observed in some, but others fail to show significant short- or long-term benefits.[58] The negative trial, however, studied only patients with chronic pain following a whiplash injury, so it is unknown if similar results will occur when treating acute pain or pain related to inflammatory joint conditions. Accordingly, reviews addressing the treatment of chronic neck pain have found little or no evidence to support the use of therapeutic IA Z-joint injections in the management of chronic neck pain.[59-61]

Cysts can arise from the facet joints, primarily in the lumbar spine, causing both mechanical and biochemical irritation of the adjacent nerves. These cysts most commonly arise from the L4-5 Z- joints[19-21, 23, 24, 26] and typically can be histologically divided into synovial and ganglion cysts.[62,63] Ganglion cysts, the less common of the two, lack a synovial lining, are typically multiloculated and do not communicate with the adjacent Z- joint.[62] Synovial cysts, which represent about 75% of Z-joint cysts,[62] have a synovial lining and communicate with the Z-joint, making them amenable to fluoroscopic visualization and rupture though needle entry into the Z-joint. Z-joint injection and cyst rupture is performed to treat not only the Z-joint arthropathy and associated pain but also is performed to rupture the associated facet cyst, thereby decompressing the nerve root in an attempt to avoid the need for a more invasive, open surgical decompression.

The use of intraarticular injections for aspiration, steroid injection and rupture of synovial cysts arising from the lumbar facet joints is well described.[19-24, 26, 64-67] These procedures are typically accompanied by transforaminal epidural steroid injections[20, 21, 67, 68] to treat the radicular pain component. However, the use of these procedures does not produce universally excellent results, and the cysts return about half of the time,[21-24, 26] necessitating the need for surgical consideration. For this reason, it is recommended that the procedure not be repeated more than once and only if the first procedure produced satisfactory results.

Medial Branch Radiofrequency Neurotomy

The facet joints are dually innervated by medial branches emanating from the dorsal rami at the two adjacent levels in the cervical spine[69] and superior levels in the lumbar spine.[70-72] Surgical investigation has revealed intraarticular nerve endings as well as neurotransmitters associated with inflammation and pain,[73-75] and animal studies have revealed the presence of mechanoreceptors.[76] Joint provocation by intraarticular injection and capsule distension has produced clinically significant pain in asymptomatic individuals.[14]

When cervical medical branch RFN is performed using appropriate anatomic technique and when the patients are selected based on response to dual confirmatory diagnostic MBB, there is consistent evidence of the treatment's effectiveness in reducing pain and disability caused by cervical Z-joint pain.[15,27] The most recent systematic review included eight primary studies.[27] This systematic review found that a majority of patients, selected based on response to confirmatory MBB, were pain free at 6 months, with a number needed to treat of 2.

In the lumbar spine, an observational study of anatomically accurate RFA demonstrated that 80% of patients experienced at least 60% pain relief, and 60% of patients obtained at least 80% pain relief lasting 12 months after RFA.[4] One randomized controlled trial employed a technique in which the RFA probes were positioned perpendicular to the medial branches. This is contrary to existing procedural recommendations as presumably only a short length of the nerve is lesioned using this approach. Indeed, the pain relief reported in the treatment arm was appreciable compared to the sham group, but as could be expected a diminishing number of patients had relief beyond 6 weeks after RFA.[77] A randomized, controlled study of anatomically correct RFA in 40 patients revealed statistically significant improvement in back pain as well as functional outcome measures at 6 months.[78] No serious adverse events or complications were reported in these trials when motor stimulation is performed prior to ablation and the patients remained awake.[79]

When medial branch RFN is performed using appropriate anatomic technique and when the patients are selected based on response to dual confirmatory diagnostic MBB, there is consistent evidence of the treatment's effectiveness in reducing pain and disability caused by Z-joint pain.[15, 27]

There is no literature addressing the use of IA injections for thoracic pain, and literature for the use of MBB or RFA for persistent pain in the thoracic spine is limited to lower level evidence from retrospective studies and case series.[80-83] Empirically, studies have demonstrated that the thoracic facets are also innervated by medial branches, though the anatomical course of these nerves is more unpredictable and varies by the given anatomical level within the thoracic spine.[84] Literature exists demonstrating efficacy of thoracic MBB and RFN, though this is limited to retrospective studies with relatively small study populations. However, there is no medical literature that suggests any other effective alternative therapy for this patient population. As such, we feel clinicians should weigh the risks and benefits of pursuing these interventions versus other palliative care in patients with thoracic spine pain who otherwise appear to have very limited remaining treatment options.

Another recent systematic reviews investigated the durability of the response and effectiveness of repeat RFA treatment in the cervical spine and lumbar spine.[28] This review found durable treatment effects, averaging nine months in patients treated in the cervical spine. It also showed that benefits were reproducible with repeat treatment, provided that response to the prior RFN was at least 3 months. Thus, medial branch RFN is indicated in patients with a diagnosis of Z-joint pain based on response to dual diagnostic MBB injections. Repeat treatment is indicated in patients who experience a return of symptoms following at least three months' relief from a previous RFN.

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Level A.	$100 to $1000	Level F.	$100,001 to $500,000
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Level C.	$10,001 to $25,000	Level H.	$1,000,001 to $2.5M
Level D.	$25,001 to $50,000	Level I.	greater than $2.5M
Level E.	$50,001 to $100,000		

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

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Boakye, Maxwell: Nothing to disclose.

Cowan, R. S.: Consulting: LDR (B); Research Support - Investigator Salary: LDR (B); Relationships Outside the One-Year Requirement: LDR (Speaking and/or Teaching Arrangement, A, dissolved 2010).

DePalma, Michael J.: Consulting: VertiFlex, Inc. (Amount not disclosed, Paid directly to institution/employer); Trips/Travel: Medtronic (Travel expenses); Board of Directors: SIS (Travel expenses, Paid directly to institution/employer), Virginia Spine Research Institute, Inc. (President and Director of Research, Paid directly to institution/employer); Scientific Advisory Board: Medtronic (Amount not disclosed), Halyard (Amount not disclosed, Paid directly to institution/employer); Research Support (Investigator Salary): Relievant (B, Paid directly to institution/employer), SI-Bone (B, Paid directly to institution/employer), Mesoblast, Inc. (B, Paid directly to institution/employer), VertiFlex (B, Paid directly to institution/employer); Research Support (Staff/Materials): Relievant (B, Paid directly to institution/employer), Mesoblast (B, Paid directly to institution/employer), SI-Bone (B, Paid directly to institution/employer), VertiFlex (B, Paid directly to institution/employer); Relationships Outside the One Year Requirement: AOI Medical (A, dissolved 2010), Stryker Interventional Spine (B, dissolved 2010), St. Jude Medical (Amount not disclosed, dissolved 2010), Kyphon/Medtronic (B, dissolved 2008), Stryker Biotech (A, dissolved 2011). ATRM (A, dissolved 2011).

Dietze, Donald: Stock Ownership: Globus Medical (<1%, Paid directly to institution/employer); Consulting: Medtronic (None, Paid directly to institution/employer), Precision Spine (None), Spinal Frontier (None).

Easa, John E.: Stock Ownership: Janus Biotherapeutics (3%, Paid directly to institution/employer).

Ghiselli, Gary: Private Investments: DiFusion (9%); Consulting: New Era Orthopedics (B).

Glaser, John A.: Nothing to disclose.

Harrop, James S.: Royalties: Jaypee Publishing (A); Consulting: DePuy Spine (C, Paid directly to institution/employer); Board of Directors: Jefferson Medical College Physician Board (None); Scientific Advisory Board: Bioventus (B, Medical Advisory Board); Other Office: Bioventus (B), Asterias (B, Data Monitoring Safety Board); Grants: AO Spine (E, Paid directly to institution/employer); Fellowship Support: NREF (E, Paid directly to institution/employer); Other: Teijin (B, Data safety monitoring board).

Holt, Timothy A.: Speaking and/or teaching arrangements: SI-Bone (E, Paid directly to institution/employer); Trips/Travel: SI-Bone (B).

Horn, Scott I.: Speaking and/or Teaching Arrangements: North American Spine Society (Travel expenses), AAPMR (Travel expenses), SIS (Travel expenses); Board of Directors: Spine Intervention Society (Health Policy Chair); Other Office: SIS (CPT Advisor).

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

intervention Society (Treasurer), Association of Academic Physiatrists (Board of Directors - Chair of Membership Committee).
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Lapinsky, Anthony S.: Nothing to disclose.
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Matz, Paul G.: Speaking and/or teaching arrangements: AO Spine North America (B).
Mayer, E. Kano A.: Speaking and/or Teaching Arrangements: North American Spine Society (Travel expenses); Trips/Travel: North American Spine Society (B); Research Support - Staff and/or Materials: SI-Bone (B, Paid directly to institution/employer).
O'Brien, David R.: Stock Ownership: OrthoCarolina (<1%), Transformant Healthcare Solutions (<1%), Arrowlytics (<1%); Trips/Travel: North American Spine Society (B); Board of Directors: North American Spine Society (Health Policy Council Director); Speaking and/or Teaching Arrangements: SIS (Travel expenses).
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Reiter, Mitchell F.: Private Investments: CreOsso (4%).
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Sanford, Timothy: Nothing to disclose.
Seldomridge, Alex: Nothing to disclose.
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Smuck, Matthew: Stock Ownership: NuSpine (1%), BlueJay Mobile-Health (1%); Private Investments: Vivametrica/Sikoya (20%, Founding partner); Trips/Travel: SIS (B), North American Spine Society (B); Board of Directors: Vivametrica/Sikoya (None), SIS (None), North American Spine Society (None); Scientific Advisory Board: NuSpine (Stock options), Lumo Body Tech (Stock options), BlueJay Mobile-Health (Stock options); Other Office: The Spine Journal (Deputy Editor), SIS (Board of Directors), North American Spine Society (Board of Directors); Other: Expert witness - State Farm (F), Expert witness - Kaiser Permanente (C); Relationships Outside the One-Year Requirement: Cytonics, Inc. (Research Support: Staff and/or Materials, F, dissolved in 2011).
Summers, Jeffrey T.: Stock Ownership: NEVRO (1%); Board of Directors: First Choice Insurance (Representative for Pain Management), SIS (Board Member and Past President, Travel expenses).
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Comments

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

NASS Coverage Recommendations Methodology

Topic Selection:
Coverage Recommendations topic lists are developed and approved by the Coverage Committee. Topics include both therapeutic and diagnostic procedures and treatments as well as nonoperative, interventional, and surgical procedures and treatments. The breadth of the topics attempts to represent all facets of spinal care. Topics are selected based on frequency of use in spine care and will attempt to represent the full breadth of procedures, diagnostics, and interventions.

Author Assignment:
The Coverage Committee members rank their preferences (1, 2, or 3) for topic assignment. The Chair matches topics to the members' preferences as much as possible. Active consideration is given to avoiding conflicts of interest, whether financial or otherwise, between members and the topics assigned. All authors disclose any conflicts of interest in accordance with the NASS disclosure policy.

Background Data Review:
For each topic, authors coordinate a literature search with the help of a research librarian/NASS staff member.

A literature search using PubMed, EMBASE, Web of Science and Cochrane is performed using search terms identified by the author specific to the topic assigned. Searches are limited to systematic reviews, meta-analyses, clinical guidelines, and most importantly, randomized controlled trials. The search produces a list of abstracts to be sent to the author for review and selection of appropriate articles for full review. Selected articles are then be sent to the Coverage Committee Chair for the approval to reduce any potential bias. The National Guidelines Clearinghouse is also be searched by NASS staff for appropriate clinical guidelines. Note that only full text, peer-reviewed articles published in English are eligible for review. Abstracts and non-published reports are not eligible for review.

In addition, NASS staff identify and retrieve any previously issued coverage policy on the topic, either by a private or public insurance provider.

Data Analysis:
The medical literature is analyzed with preference given to the highest quality literature available. Funding and other potential sources of bias are taken into consideration, as is consistency of the literature reviewed. In the absence of high-level data, coverage recommendations reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States.

Coverage Recommendations Formulation:
When trials, guidelines, or systematic reviews are available, the coverage recommendations should reflect the published data as much as possible. However, given the complexities of clinical care and the limitations of the medical literature in many circumstances, additional consideration is given to specific clinical scenarios and the currently available treatment options for those scenarios, including the potential risks and benefits of the alternative treatment options, prior to establishing a coverage decision. In summary, final determinations are made upon an evidence-based review of the existing data, an understanding of clinical care, and the NASS mission.

Individual coverage recommendations follow a standard format document approval: Once formulated, the coverage recommendations are reviewed and revised by the Coverage Committee Chair incorporating any new data if available since the document is developed and with modifications for format. The document is then sent to the senior reviewers of the Coverage Committee and subject-matter experts from the NASS' Payor Policy Review Committee (PPRC) for review and comment. After review at this level, final modifications are made and author is advised. The proposed coverage document is sent to the NASS Executive Committee of the board directors for review and final approval before publication. The proposed coverage document is published on NASS' website with a 30-day public comment period. At the end of the public comment period, comments are reviewed and considered by the NASS Coverage Committee. Where appropriate, the Committee makes edits and then publish the final document on NASS website.

Clinical Guidelines

Diagnosis and Treatment of Adult Isthmic Spondylolisthesis

Diagnosis and Treatment of Degenerative Spondylolisthesis (Revised 2014)

Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy

Antibiotic Prophylaxis in Spine Surgery (Revised 2013)

Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (Revised 2011)

Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders

Antithrombotic Therapies in Spine Surgery

Appropriate Use Criteria

Cervical Fusion

Coding FAQs (NASS Member Resource Only)

Patient Education Brochures (Complete Catalog)

NASS Coverage Policy Recommendations

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