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Review Article

OXFORD

SPINE SECTION

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

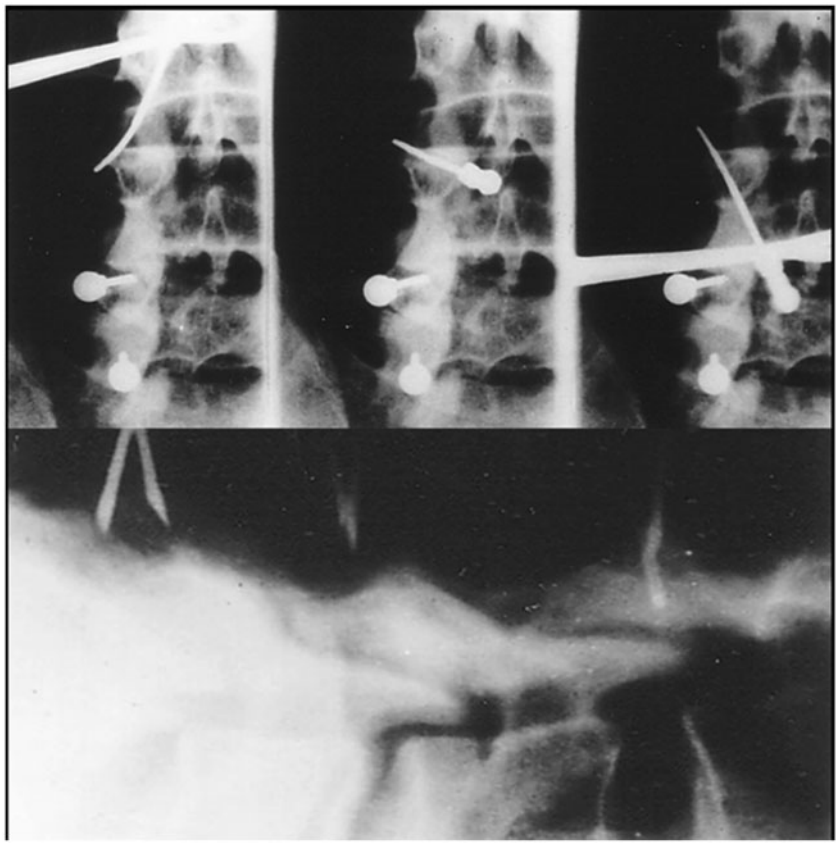

Figure 1. Radiographs illustrating the placement of electrodes using the technique of Shealy (Radionics).

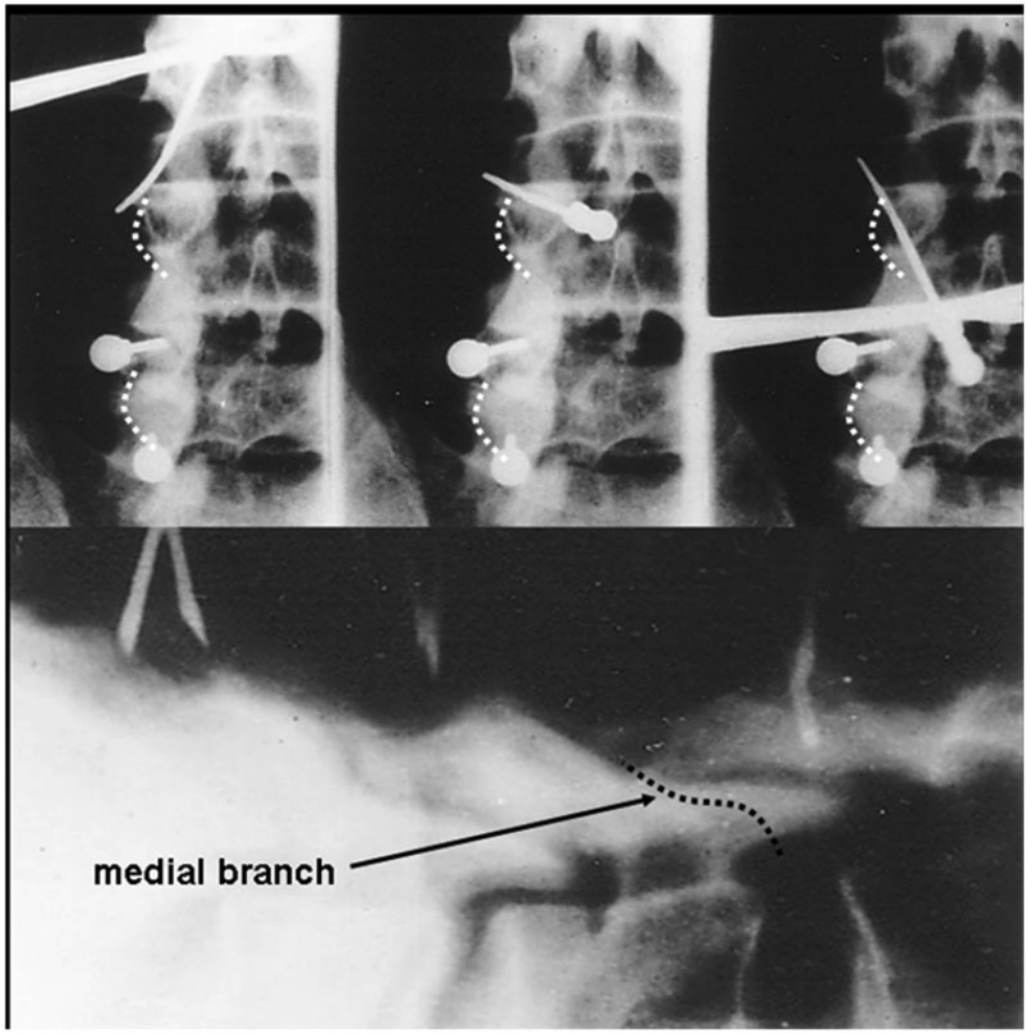

Figure 2. Copies of the radiographs of the Shealy technique (Figure 1), onto which the courses of the target medial branches have been drawn. At no placement of electrodes does the tip reach the nerve.

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,

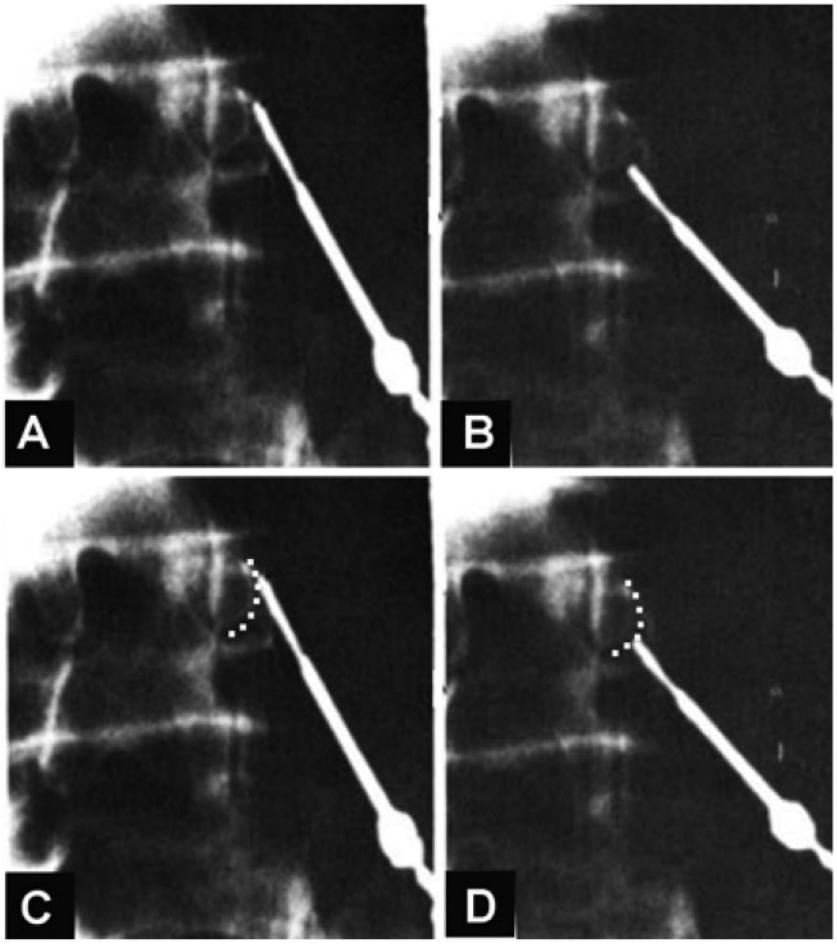

Figure 3. Radiographs of electrodes placed for lumbar radiofrequency neurotomy, published in 1979 [60]. A and B) Copies of the original radiographs. The technique recommends placing a lesion proximally and distally along the course of the nerve. In (C and D), the course of the medial branch has been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

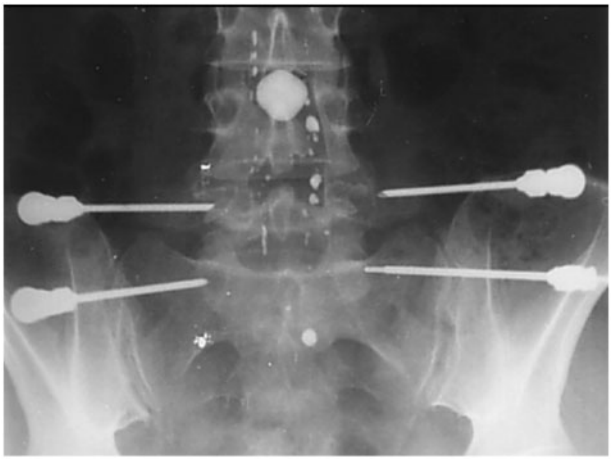

Figure 4. A radiograph of placement of guide cannulae and an electrode for lumbar medial branch radiofrequency neurotomy, published in 1980 [59].

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

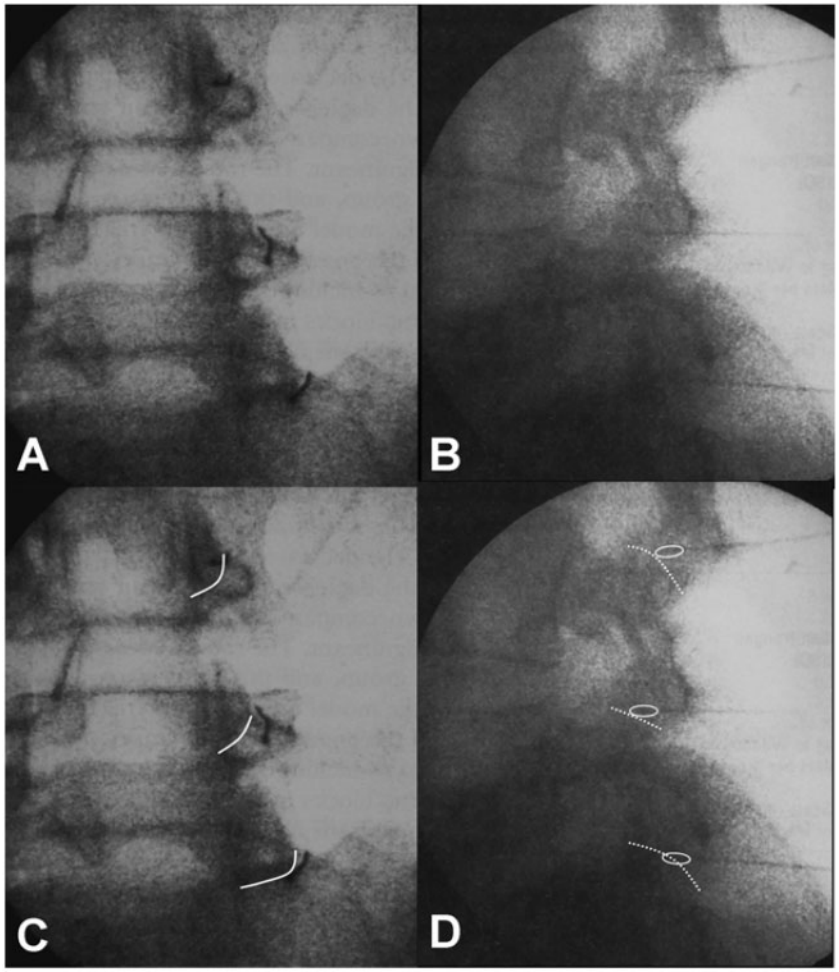

Figure 5. Radiographs illustrating an early technique for lumbar radiofrequency neurotomy using perpendicular placement of electrodes [61]. A and B) Copies of the original illustrations as published, showing antero-posterior and lateral views of electrodes placed on the L3, L4, and L5 target nerves. 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

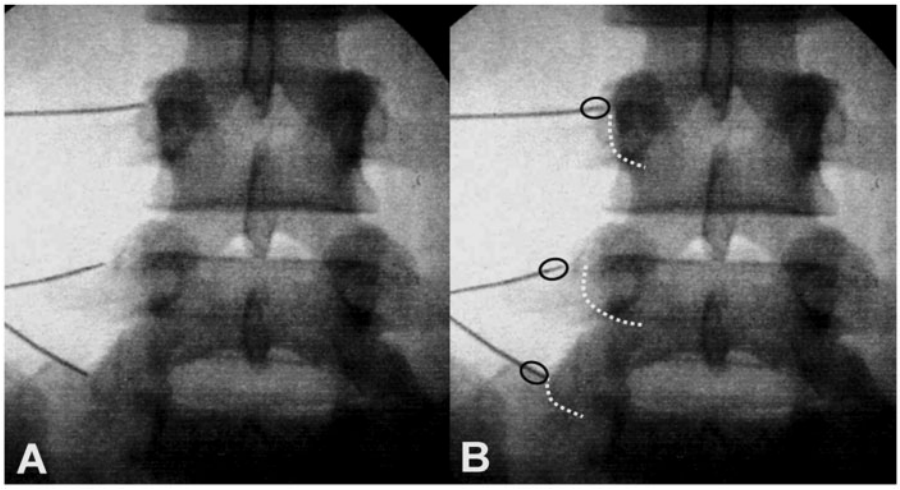

Figure 6. Radiographs of a second perpendicular technique [62]. A) A copy of the original illustration. In (B), the courses of the medial branches have been added as white dotted lines; the sizes of the thermal lesions made by the electrodes are shown as black ellipses. The electrode for the L4 medial 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.

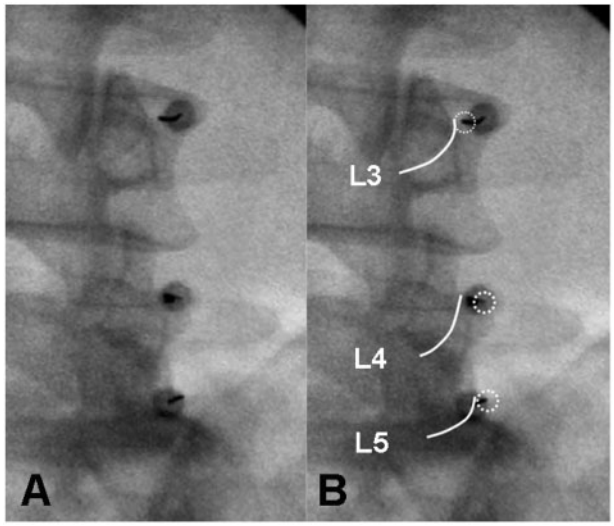

Figure 7. Radiographs illustrating electrode placement from the procedural guidelines of a recent study of lumbar radiofrequency neurotomy using perpendicular placement of electrodes [63]. A) A copy of the original published radiograph. In (B), the courses of L3 and L4 medial branches and the L5 dorsal 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.

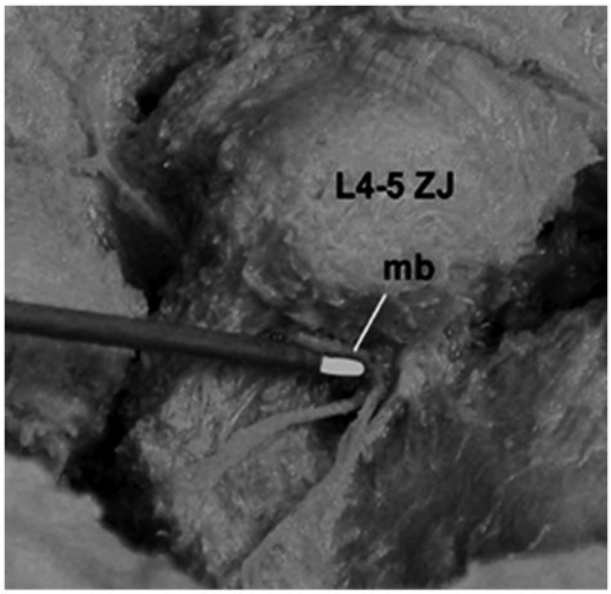

Figure 8. A close-up view of a dissection of the branches of a right L4 dorsal ramus, with the medial branch labeled (mb), crossing the neck of the L4-5 zygapophysial joint (ZJ). A 16-gauge radiofrequency electrode has been placed parallel to and in contact with the medial branch. The 5-mm active tip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

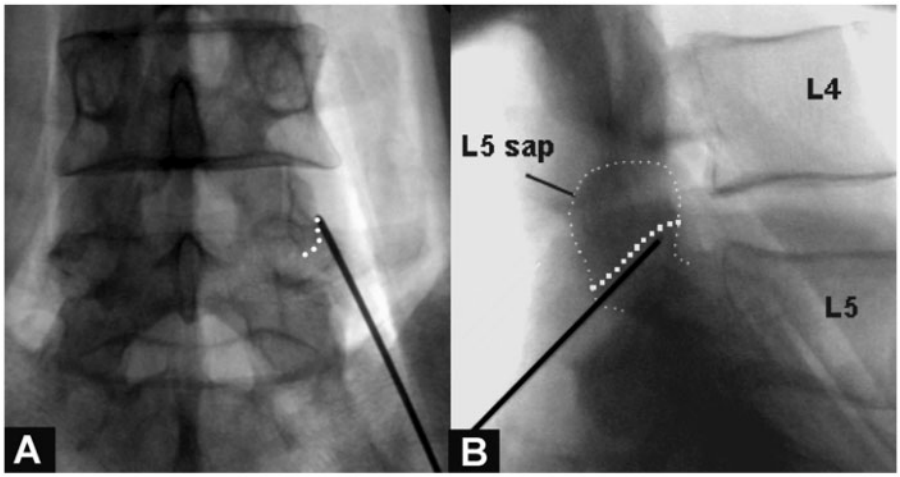

Figure 9. Radiographs of a cadaver in which an electrode has been placed parallel to and in contact with an L4 medial branch, as illustrated in Figure 1. The white dotted line depicts the course of the medial branch. A) Anteroposterior view. B) Lateral view, showing the nerve and electrode crossing the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

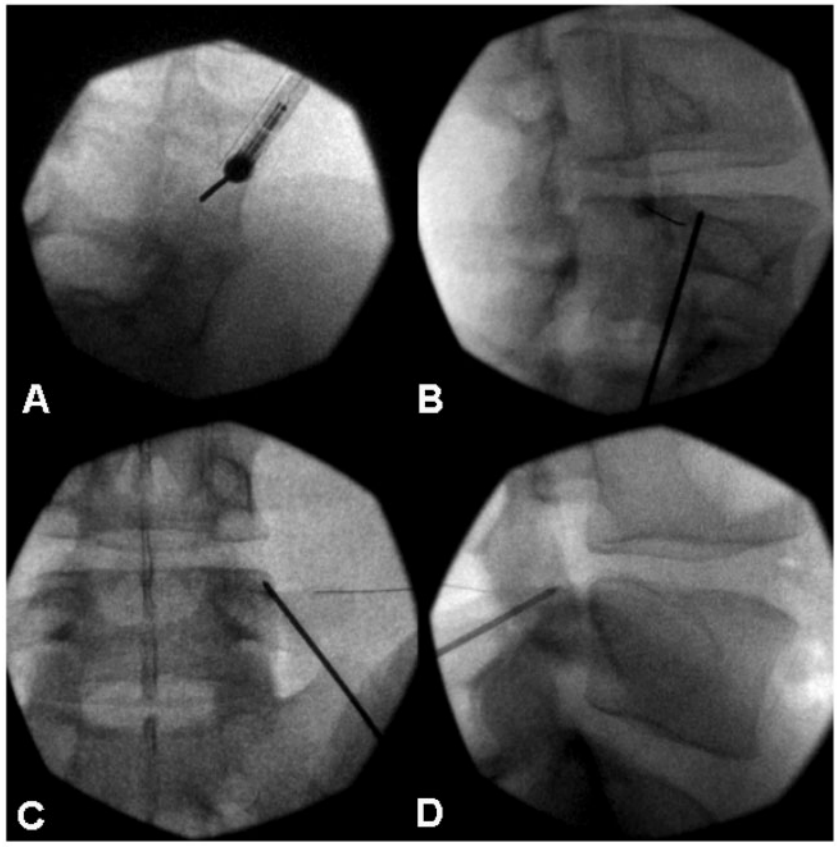

Figure 10. Radiographs of an electrode in place against an L4 medial branch, taken during an actual procedure. A) Declined view, showing an electrode against the neck of the superior articular process of L5. B) Oblique view, showing the electrode crossing the junction of the superior articular process 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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