

SPINE SECTION

Review Article

A Narrative Review of Lumbar Medial Branch Neurotomy for the Treatment of Back Pain

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ABSTRACT

Background. Confusion persists concerning the nature and efficacy of procedures variously known as facet denervation, lumbar medial branch radiofrequency neurotomy, and radiofrequency neurotomy or denervation for the treatment of back pain. Systematic reviews have not recognized the importance of patient selection and correct surgical technique when appraising the literature. As a result, negative conclusions about procedures have been drawn because lack of efficacy of one procedure has been misattributed to other, cognate, but different procedures.

Objectives. To demonstrate how the rationale and efficacy of lumbar medial branch neurotomy depends critically on correct selection of patients and use of surgically correct technique.

Methods. A narrative review and description of the available evidence, drawn from the personal libraries of the authors and from the bibliographies of systematic reviews.

Results. Three studies, commonly accepted as evidence of lack of effectiveness, were not valid tests of lumbar medial branch neurotomy because of errors in selection of patients or errors in surgical technique, or both. Two descriptive studies and three controlled studies that used valid or acceptable techniques consistently showed that lumbar medial branch neurotomy had positive effects on pain and disability. All valid, randomized controlled trials showed medial branch neurotomy to be more effective than sham treatment.

Discussion. Negative results have been reported only in studies that selected inappropriate patients or used surgically inaccurate techniques. All valid studies showed positive outcomes that cannot be attributed to placebo. Inappropriate conclusions have been drawn by systematic reviews that misrepresent invalid studies as providing evidence against the efficacy of lumbar medial branch neurotomy.

Key Words. Back Pain; Treatment; Radiofrequency; Neurotomy; Denervation

Introduction

Confusion has arisen about a family of procedures variously known as lumbar facet denervation, lumbar medial branch neurotomy, lumbar radiofrequency (RF) neurotomy, or lumbar RF neurotomy, among other names. As a result of this

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confusion, these procedures have frequently been misrepresented, with the attributes of one being mistakenly applied to another, particularly in systematic reviews. Despite the efforts of some commentators [1–3], the confusion and misrepresentation continue.

Systematic reviews were devised in order to provide a synthesis of the best available evidence about treatments. However, the methodology of systematic reviews was based on methods used for drug trials. Drugs have a consistent effect; their use is not operator-dependent. Consequently, in the case of drug trials, systematic reviews could focus on outcomes and important variables such as blinding, randomization, statistical power, validity of outcome measures, and effect sizes, without regard to the intervention itself. Furthermore, in the fields of musculoskeletal medicine and pain medicine, systematic reviews have been performed typically of interventions for conditions defined by a single symptom, such as back pain or shoulder pain. Interventions such as physical therapy, manual therapy, drugs, exercises, or acupuncture have not been applied to patients who must satisfy criteria for a particular, patho-anatomic diagnosis.

In contrast to drug trials, the outcomes of minimally invasive interventions, irrespective of randomization, can be confounded by errors in diagnosis, errors in treatment, and operator competency. Contemporary systematic reviews do not accommodate these confounding variables. They are performed without regard to such errors, as if these errors are not germane to conclusions about efficacy. With respect to lumbar medial branch neurotomy, these errors are not just relevant, they are crucial.

Any review of the literature on this topic needs to question domains not considered by conventional systematic reviews. Unless this is done, the conclusions drawn by systematic reviews may be erroneous. More egregiously, a danger arises when authorities responsible for recognition and reimbursement of procedures take the conclusions of systematic reviews literally and at face value, without realizing their omissions and limitations.

Accordingly, this narrative review has been composed to highlight the shortcomings of systematic reviews to date. It has been composed by authors who, to various extents, have been involved in the development and evaluation of the procedure. The review serves to clarify the procedure itself, and to provide evidence of its efficacy. Importantly, this review does not apply to pulsed RF. The latter is a separate procedure, not

synonymous with thermal RF neurotomy, and has been addressed elsewhere [4].

On the one hand, a narrative review composed by authors with content expertise might seem to affront the contemporary fashion for arm's length appraisal by disinterested parties with expertise in the methodology of reviews. However, content-expertise is what has conspicuously been lacking in previous reviews, which results in misconceptions and misrepresentations. Readers concerned about bias can judge for themselves by consulting the primary evidence and determining if it has been represented and interpreted fairly.

Methods

The literature pertaining to the index procedures was harvested from the personal libraries of the authors, who had been involved in the field since its inception, and who had published several of the seminal studies. That literature was cross-referenced against the bibliographies of all systematic reviews published to date on the topic [5–11].

Historical Perspective

A historical perspective is pertinent because it illustrates several flaws in past practice that have been repeated, and which affect the assessment of contemporary practices. Neither these flaws, nor their repetition, have been recognized or acknowledged by systematic reviews.

Although the proposition that the lumbar zygapophysial joints might be a source of back pain had been articulated several decades previously [12], it was not until 1971 that a method was described by which to treat this particular source of pain. Skyrme Rees [13,14] claimed that back pain stemming from the lumbar zygapophysial joint could be treated by severing the articular nerves that innervated these joints, using a special scalpel to make longitudinal incisions through the back muscles. The procedure was called “rhizolysis” [13,14]. Conspicuously, no diagnostic criteria were applied or required. Patients were treated presumptively. Astoundingly high success rates were claimed [12,13]. Others adopted the procedure, and although their success rates were more modest, they were nonetheless substantial [15–18].

An anatomical study subsequently showed that this intervention was without foundation [19]. The articular nerves that Rees claimed could be severed did not run where he depicted them. They were too deep to be reached by the blade that he used, and they ran longitudinally, rather than transversely,

and could not be transected by longitudinal incisions. Consequently, the results claimed for rhizolysis could not be attributed to the denervation of lumbar zygapophysial joints. Although this was pointed out in the literature [20,21], no explanation for the effect has been forthcoming other than a placebo effect. Irrespective of the actual explanation, this experience with “rhizolysis” warns that poorly conducted studies can report good outcomes in 48% [16] or 62% [14,17] of patients for a procedure with a false anatomical basis.

Inspired by the publications of Rees [13,14], Shealy modified the intervention by using RF electrodes purportedly to coagulate the articular nerves and thereby to denervate painful lumbar zygapophysial joints [22–25]. His procedure became known as facet denervation. He claimed impressive success with this operation, and others echoed this success [26–38].

In due course, however, it was demonstrated that no nerves were located where Shealy described placing his electrodes [39,40]. Therefore, the outcomes of his procedure could not be attributed to denervation of painful lumbar zygapophysial joints. This revelation was not heeded, and publications worldwide continued to report the success of lumbar facet denervation [41–45]. As a result of this endorsement facet denervation became an “accepted” practice in the United States, despite having had its anatomical basis refuted.

In order to distinguish it from “facet denervation” as described by Shealy [22–25], the procedure corrected for surgical anatomy was named lumbar medial branch neurotomy [39,40]. The targets for denervating lumbar zygapophysial joints were not articular nerves, but the medial branches of the lumbar dorsal rami (or the dorsal ramus itself, at L5), which furnished articular branches to these joints. The pivotal revision was that if operators sought to denervate the joints they should place their electrodes accurately on the target nerves.

A later revision pertained to the orientation of electrodes. It had been common practice to place electrodes perpendicular to the target nerve, in the same manner in which hypodermic needles might be placed in order to anesthetize the nerve. The assumption was that RF electrodes coagulated distal to their tip. This assumption proved wrong.

Disappointed at the short duration of relief obtained in their patients following lumbar medial branch neurotomy, investigators examined the nature of the lesions produced by their electrodes [46]. In experimental media, they found

that RF electrodes produced substantial lesions circumferentially in a transverse direction around the active tip of the electrode, but very little lesion distally [46]. Placing the electrode perpendicular to the nerve risked having the lesion miss the nerve altogether, or at best incorporating it with no more than a “spot” lesion. Consequently, it was recommended that electrodes should be placed parallel to the target nerve, in order to achieve coagulation along a substantial length of the nerve [46].

The concept validity of this recommendation seemed obvious, and its face validity, was implicit. However, not all operators adopted the recommendation. This prompted a reaffirmation of the recommendation, some 20 years later, together with a demonstration of its face validity in a radiographic cadaver study [47]. As well, it was shown that accuracy of coagulation depended critically on the size of the electrode used. Large gauge electrodes (16G) could be relied upon to capture the target nerve, because the lesion produced was large. Smaller gauge electrodes (21G), however, need to be placed exactly on the nerve for them to have any prospect of capturing the nerve. A displacement as little as 1 mm could result in the lesion produced failing to encompass the target nerve [47].

Despite these recommendations, operators—particularly in The Netherlands and Europe—preferred to continue with perpendicular placement of their electrodes [48]. If placed in this manner, exactly on the target nerve, electrodes could possibly succeed in coagulating the nerve. However, the length of the lesion produced would be short, which theoretically would result in limited duration of relief. The shorter the length of nerve coagulated, the sooner it would repair, and the shorter the duration of relief obtained. Otherwise, if the electrode placed perpendicular to the nerve was not placed exactly on the nerve, the lesion made could fail to incorporate the nerve. This would limit the yield of the procedure and its success rate.

Standards

In the light of this history, the International Spine Intervention Society prescribed certain standards of practice for lumbar medial branch RF neurotomy [49]. It recommended that, for lumbar medial branch neurotomy to be anatomically accurate, electrodes should be placed parallel to the target nerve. Furthermore, operators should understand that small electrodes might fail to

capture the nerve. They could not rely on single placements of the electrode. Multiple placements might be required in order to cover all possible, albeit small, variations in the exact location of the nerve. Also, lesions should be placed along the maximal available length of the nerve, in order to optimize duration of effect.

Diagnostic Criteria

The paradigm of lumbar medial branch neurotomy is that a patient's pain can be relieved by coagulating the nerves that mediate (transmit) their pain. An essential prerequisite, therefore, is that it must be shown that the target nerves are responsible for the patient's pain. This is achieved by controlled diagnostic blocks of the medial branches of the lumbar dorsal rami that mediate the pain [50].

Medial branch blocks involve anaesthetizing the nerve with a tiny volume of local anaesthetic, as a test to see if doing so relieves the patient's pain. Single diagnostic blocks are not valid, because they carry an unacceptably high false-positive rate [51–53]. In order to reduce the likelihood of responses being false positive, controlled blocks are mandatory [50].

For various reasons, medial branch blocks are the only acceptable and validated diagnostic test as an indication for medial branch neurotomy. First, there is the logic that before a nerve is coagulated, in the name of treatment, it should be shown that blocking the nerve temporarily relieves the patient's pain. There is neither logic nor merit in "treating" a nerve that has not been shown to be relevant to the patient's complaint. Second, medial branch blocks have been validated for face validity [54], target-specificity [55], and construct validity [51]. Third, they are predictive of outcome from medial branch neurotomy [56]. Patients with positive responses to controlled blocks can expect to have substantial and lasting responses to medial branch neurotomy [56].

No other diagnostic test pertinent to medial branch neurotomy has been evaluated, let alone vindicated, for construct validity or predictive validity. In particular, intra-articular blocks of the lumbar zygapophysial joints have not been validated. Intra-articular blocks have not been subjected to controls, and have not been shown to be predictive of response to any form of treatment.

The foremost diagnostic criterion for lumbar medial branch neurotomy, therefore, is relief of pain following controlled medial branch blocks [49,50]. Blocks that are not controlled, or intra-articular blocks, are not a substitute, for they lack

validity. If controlled blocks are not performed the risk obtains that patients will undergo treatment for a condition that they do not have and, therefore, are destined to failure or to no more than a placebo response.

What remains contentious is the degree of relief that should occur. Ideally, diagnostic blocks should produce complete relief of pain, or near complete relief. This would occur when the patient's sole or principal source of pain lies in the joints innervated by the nerves blocked. Under this criterion, complete relief or near complete relief of pain can be expected from medial branch neurotomy. Some investigators, however, use a more liberal criterion, such as greater than 50% relief of pain. This criterion allows medial branch neurotomy to be used to provide substantial, but not necessarily complete, relief of pain, which is nevertheless clinically worthwhile.

Efficacy

Earlier publications no more than described the theoretical basis of lumbar medial branch neurotomy [39,40]. The first clinical study that used appropriate selection criteria and that used correct surgical technique was a descriptive study [56]. To be eligible for treatment, patients had to report at least 80% relief of pain following controlled medial branch blocks. Following treatment, some 60% of patients obtained at least 80% relief of their pain, lasting at least 12 months, and 80% of patients sustained at least 60% relief [56]. This relief of pain was accompanied by improvements in disability that were both clinically and statistically significant.

Similar outcomes were corroborated by another descriptive study [57]. During a 10-year period, patients were selected on the basis of at least 70% relief of pain following controlled medial branch blocks. Of the 209 patients treated by lumbar medial branch neurotomy, 174 were reviewed. Of these, 68% (or 56% of the original sample) maintained at least 50% relief of their pain for between 6 and 24 months. Pain relief was associated with improved activities and decreased consumption of analgesics.

A third study selected patients on the basis of at least 50% relief of pain following both a medial branch block and an intra-articular block. It showed that medial branch neurotomy achieved significant reductions in pain, improvements in disability, and reduced analgesic requirements [58]. These effects peaked at 3 and 6 months, but

attenuated thereafter. The study recorded high patient satisfaction with the procedure.

Descriptive studies such as these are not admitted as evidence by systematic reviews, which restrict their purview to randomized controlled trials. However, the virtue of descriptive studies is that they establish a benchmark: of what outcomes can be achieved if patients are correctly selected and if a valid surgical technique is correctly applied.

Many of the studies accepted by systematic reviews are not valid studies of lumbar medial branch neurotomy. They fail either in selection or surgical technique or both.

The study of Gallagher et al. [44] was not a test of lumbar medial branch neurotomy. In the first instance, it selected patients on the basis of single, uncontrolled, intra-articular, diagnostic blocks. Therefore, the patients enrolled were not necessarily ones who would be expected to respond to medial branch neurotomy. Second, the study explicitly used the technique of Shealy [22–25], which has been discredited [39,40]. In essence, it was a study that used a flawed surgical technique to coagulate nerves that were not shown to mediate the patients' pain.

The study of Leclaire et al. [59] was not a test of lumbar medial branch neurotomy. Controlled blocks were not used. Medial branch blocks were not used. The investigators relied on delayed responses to intra-articular injections of steroids, which have been shown to be no more effective than placebo [60]. Therefore, the patient sample did not necessarily have pain that was amenable to treatment by medial branch neurotomy, and was unlikely to be so. Furthermore, the operative technique was not described. The outcome data strongly suggest that it was an inaccurate technique. The active treatment group did not achieve outcomes anywhere near the benchmark standard for lumbar medial branch neurotomy [56]. Indeed, the success rate was minimal to zero, and less than that of the placebo group. This suggests that one sham treatment was compared with another sham treatment. In order for a controlled trial to be an adequate test of an intervention, that trial should achieve outcomes at least comparable with those evident in the descriptive literature. Zero outcomes from active treatment strongly suggest a surgical flaw.

The study of van Wijk et al. [61] was not a test of lumbar medial branch neurotomy. However, it was expressly and explicitly a test of how RF neurotomy is practiced in The Netherlands, with respect to both selection of patients and surgical

technique used [61]. The results were negative: active treatment was not detectably more effective than sham treatment. Explicitly, therefore, the conclusion is that the manner in which neurotomy is practiced in The Netherlands is no more effective than placebo.

The fatal flaws in the study were that patients were not selected using controlled medial branch blocks, and that a highly inaccurate surgical technique was used. This was evident in the illustrations of the publication, as demonstrated in a letter to the editor following publication of the study [62]. Electrodes were placed in locations remote from the target nerves, with little to no prospect of coagulating the nerves. Consequently, the study amounted to comparing one sham treatment with another.

The study by van Kleef et al. [63] was suboptimal in certain respects but more informative and relevant than others. It did not select patients on the basis of controlled diagnostic blocks, but nevertheless did require at least 50% relief of pain following a single diagnostic blocks. An effect of this limitation is that whereas some of the patients recruited possibly did have pain amenable to treatment by lumbar medial branch neurotomy, it is also possible that others did not. Therefore, a low success rate should be expected. This expectation was reflected in the data. As well, the surgical technique used involved perpendicular placement of electrodes, but the illustrations of the procedure are compatible with accurate placement on the target nerve. The effect of this limitation would be that although relief might occur its duration would be less than that achieved in benchmark studies. This, too, was reflected in the data.

Only a minority of all patients treated achieved complete relief of pain or at least 50% relief, and few had enduring relief. Nevertheless, active treatment was superior to placebo treatment. Of the 15 patients treated with active neurotomy, 7 (47%; 22–72%) achieved relief, compared with 3 out of 16 patients (19%; 0–38%) treated with placebo [63]. Although these proportions are palpably different, they are not significantly different statistically, for their 95% confidence intervals overlap. However, survival analysis over the ensuing 12 months showed a significant difference ($P = 0.002$) in favour of active treatment [63], with a number needed to treat of 4. This relief of pain was accompanied by significant improvements in disability, and reduction in the consumption of analgesics [63].

The study of van Kleef et al. [63] was not an example of correct selection of patients or of optimal technique. Quantitatively, therefore, its outcomes are less favourable than those reported in descriptive studies. However, the use of randomization made the study a valid test of medial branch neurotomy against placebo. It serves to show that the outcomes reported by descriptive studies cannot be summarily dismissed and attributed to untested placebo effects.

A similar contribution was provided by Nath et al. [64]. These investigators studied a particularly difficult sample of patients, who had multiple sources of pain. Pain mediated by the lumbar medial branches was only one of several types of pain suffered. Nevertheless, the patients were confident in being able to distinguish that pain relieved by medial branch blocks, and subsequently by medial branch neurotomy. The particular virtues of this study were that controlled diagnostic blocks were used to select patients and that optimal technique [49] was used. Patients had to report at least 80% relief of the particular pain that was to be treated. After treatment, complete and enduring relief of pain was not demonstrated, because the patients still had other sources of persisting pain. However, for the pain for which patients were treated, the study showed significantly greater improvements following active medial branch neurotomy compared with sham treatment. Therefore, the effects of RF neurotomy cannot be wholly attributed to placebo effects. Relief of pain was accompanied by reduction in the use of analgesics [64].

In another study [65], the primary objective was to evaluate a new procedure—pulsed RF—whose efficacy is not known [4], by comparing it with conventional, i.e. thermal, RF neurotomy. That study, however, provided outcome data and controlled data concerning conventional lumbar medial branch neurotomy, irrespective of the comparison with pulsed RF. The study enrolled patients who obtained at least 50% relief of pain following single, uncontrolled, diagnostic blocks [65]. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. Patients were then randomized for treatment by either thermal or pulsed RF, but for thermal RF a correct technique was used. The electrode was placed parallel to the target nerves. As well, the study included a group who underwent sham treatment, in which the electrode was placed as for thermal RF but no lesion was generated. For the relief of pain,

thermal RF was significantly more effective than sham treatment immediately after treatment, at 6 months, and at 1 year; and thermal RF was significantly more effective than pulsed RF at 6 months and at 1 year [64]. For improvement in disability, thermal RF was more effective than sham treatment immediately after treatment, at 6 months, and at 1 year; and thermal RF was more effective than pulsed RF at 1 year [65]. After treatment, 95% (85–100%) of patients who underwent sham treatment still required analgesics, compared with only 40% (18–61%) of those treated with thermal RF. Of those who underwent sham treatment, 20% (2–38%) reported an excellent outcome, compared with 65% (44–86%) of those treated with thermal RF.

Notwithstanding what the authors sought to conclude about pulsed RF, their data clearly show that conventional lumbar medial branch neurotomy was significantly more effective than sham treatment, for relief of pain, improvement in disability, use of other health care, and global satisfaction. Pulsed RF appeared to be effective immediately after treatment, but had no enduring effects. Therefore, pulsed RF is not a substitute for conventional, thermal, lumbar RF medial branch neurotomy.

By definition, medial branch neurotomy is not a permanent cure for pain. It is natural, and to be expected, that the coagulated nerve will regenerate. In that event, however, the procedure can be repeated [66], and relief reinstated. Repeat treatment can be justified if previously the patient has reported satisfying relief from pain, corroborated by restoration of function, and return to work—if socioeconomically possible.

When performed correctly, lumbar medial branch neurotomy is a remarkably safe procedure. Side effects are uncommon [67], of limited duration, and minor in nature, as might be expected of a minor neurosurgical procedure. They include soreness from the electrode track and temporary pain from the sites where lesions are placed. Major complications have been encountered only when operators have failed to follow guidelines for the safe and accurate conduct of the procedure [68].

Discussion

The acme of evidence-synthesis is meta-analysis, by which results from multiple studies can be pooled in order to consolidate trends in the literature. But meta-analysis requires that studies be totally homogenous in terms of samples and

methods. Rarely has this been the case in pain medicine.

Instead, systematic reviews typically undertake a “head count,” balancing the number of positive studies against the number of negative studies. By this process, the evidence can be said to favour an intervention if positive studies outnumber negative ones; or be “conflicting” or “inconclusive” when the numbers are equal. Errors arise, however, if positive studies are overlooked, ignored, or discredited, whereas negative studies are accorded undue prominence. This process becomes particularly egregious when negative studies that are fundamentally inadmissible are nevertheless accepted as evidence simply because of their negative result. This suggests either a bias against the procedure or a lack of insight into it.

In the law, two standards of evidence apply. For criminal proceedings the standard is “beyond all reasonable doubt.” For lesser proceedings the standard is “on the balance of probabilities.” The former standard is sometimes the level of evidence called for by systematic reviews and critics, but is very costly to achieve in studies of Pain Medicine. The latter standard is far more reasonable and practical. Moreover, it translates into a form of Bayesian logic when applied to pain medicine. It asks what the likelihood is that a procedure works, before it is tested; and whether the evidence subsequently moves one to affirm or reject that view.

In the case of lumbar medial branch RF neurotomy, the procedure is conceptually sound; it has a plausible, biological rationale. Diagnostic blocks show that the patient’s pain can be interrupted, albeit temporarily. RF coagulation has the ability to prevent conduction along nerves for periods longer than does a local anaesthetic agent. RF neurotomy, therefore, should provide prolonged relief. The a priori expectation, therefore, is that this treatment should work. The subsequent question is whether the evidence contradicts this expectation or is compatible with it.

Pivotal to evaluating the evidence is the realization that medial branch neurotomy is not a treatment for any form of back pain. It is a treatment for

a particular form of back pain. Under those conditions it is not a valid criticism of a study that patients were “highly selected.” The paradigm of medial branch neurotomy demands that patients be highly selected. A complement to this requirement is that the intervention cannot be tested in patients who have not been properly selected. Nor can it be tested if surgically inaccurate techniques are used.

In this regard, the evidence shows that RF “treatment” fails when patients are wrongly selected or when inaccurate technique is used. Others have identified these reservations [69], but they are no longer a matter of theory, opinion or choice. The evidence explicitly shows that when patients are selected by intra-articular injections [59], or when unvalidated [59,61] techniques are used, RF “treatment” does not work. But this does not constitute evidence against procedures that are performed properly. Yet reviews in the past admitted procedurally flawed studies [5–7], and continue to do so [8–11], giving them equal status, as evidence, to procedurally valid studies. Some reviews [8,9] cite only the flawed studies [44,59,61], to the exclusion of valid studies [62,65], in order to emphasize their negative or neutral results, seemingly to justify drawing negative conclusions about the procedure. Even when all studies have been considered [7,10], the inclusion of procedurally flawed studies speciously dilutes the evidence to inconclusive or conflicting. Studies that are flawed in patient selection or surgical technique (Table 1) do not provide admissible evidence, and should be disregarded by systematic reviews.

Whenever patients have been correctly selected, and when anatomically accurate surgical techniques have been used, the pre-test expectations of success have consistently been vindicated (Table 2). Lumbar medial branch neurotomy achieves relief of pain, improvements in disability, and reductions in the need for analgesics. No evidence stemming from valid studies refutes the pre-test expectations. In Bayesian terms, therefore, the evidence fails to refute the pretest expectations that the treatment should work and, indeed, consistently corroborates that expectation.

Table 1 A summary of the technical flaws of invalid studies of lumbar medial branch neurotomy

Study	Patient Selection		Surgical Technique
	Medial Branch Blocks	Controlled Blocks	
Gallagher et al. [44]	No	No	Discredited. Lesions not placed accurately on target nerves.
Leclaire et al. [59]	No	No	Unknown
van Wijk et al. [61]	No	No	Inaccurate. Lesions not placed accurately on target nerves.

Table 2 A summary of the validity of studies of lumbar medial branch neurotomy, and the outcomes of the valid studies

Study	Level of Evidence	Patient Selection			Outcomes				
		Medial Branch Blocks	Controlled Blocks	Surgical Technique	Better than Sham	Success Rate	Pain Relief	Improved Disability	Reduced Analgesics
van Kleef et al. [63]	II	Yes	No	Partially valid	Yes	47%	Yes	Yes	Yes
Tekin et al. [65]	II	Yes	No	Valid	Yes	65%	Yes	Yes	Yes
Nath et al. [64]	II	Yes	Yes	Valid	Yes		Yes		Yes
Dreyfuss et al. [56]	IV	Yes	Yes	Valid		80%	Yes	Yes	
Gofeld et al. [57]	IV	Yes	Yes	Valid		56%	Yes	Yes	Yes
Burnham et al. [58]	IV	Yes	Partial*	Valid		43%	Yes	Yes	Yes

* The study of Burnham et al. [58] required a positive response to both a medial branch blocks and an intra-articular block. Levels of Evidence: I: Systematic review of controlled trials, II: randomized controlled trial, III: case-control study, IV: descriptive outcome study.

Not all studies have tested how well medial branch neurotomy works, in terms of optimal success rates and lasting effect. Only the studies of Dreyfuss et al. [56], Gofeld et al. [57], Burnham et al. [58], and Tekin et al. [65] used correct technique; achieved lasting outcomes, and provided long-term data (Table 1). However, three randomized studies have shown that active treatment is more effective than sham treatment [63–65]. This is a crucial step in the assessment of the procedure. This evidence vaccinates the results of descriptive studies [56–58] against being dismissed as due to placebo effects. In contrast, no valid study has shown that medial branch neurotomy is a placebo.

What might be of concern to insurers and others who pay for these procedures are standards of practice. As the literature describes erroneous practices in selection and technique, insurers and others can expect similar aberrations in the communities that they service. It is for this reason that the International Spine Intervention Society sought to prescribe appropriate, evidence-based guidelines for how medial branch blocks and medial branch neurotomy should be conducted. It is not an indictment of the procedure if practitioners do not perform it as recommended. That is a matter of discipline. If insurers and others are concerned about abuses and lack of discipline, the problem is not one of science and evidence; it becomes a matter of quality assurance. Seeking to discredit a procedure by incomplete or erroneous reviews of the purported evidence is neither honourable nor helpful. It disadvantages worthy patients and responsible practitioners. An alternative solution is available.

Procedures performed according to guidelines should be supported. Those that deviate from guidelines should not. The guidelines published by the International Spine Intervention Society [49,50] provide the means by which that distinction can be made.

The evidence requires that the singular indication for lumbar medial branch neurotomy is a positive response to controlled diagnostic blocks [50]. If controlled blocks are not allowed by administrations, single blocks are possibly tolerable, but the consequence is that samples of patients selected for treatment will be contaminated by patients who would not qualify under more rigorous conditions. Therefore, lesser success rates should be expected. Nevertheless, worthy patients would not be denied care. Subsequently, the surgical technique should be consistent with the known anatomy and rationale for the procedure [49]. What makes a procedure a correct lumbar medial branch neurotomy is not what it is called but how it is executed.

Nor should insurers fear being overwhelmed by an unaffordable avalanche of neurotomies. Among injured workers with back pain, pain amenable to medial branch neurotomy is uncommon to rare [3,70], when stringent diagnostic criteria are applied. It is common only amongst elderly patients [3,71]. Excesses in medial branch neurotomy occur only if responsible diagnostic criteria are not applied or if correct practice is not enforced.

As a guide to consumers, practitioners, and regulators, the Appendix summarizes the critical criteria for optimal selection of patients and optimal surgical technique in the conduct of lumbar medial branch neurotomy.

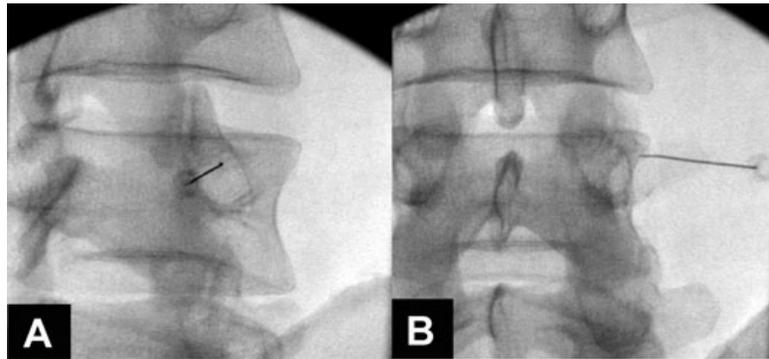
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Figure 1 Fluoroscopy views of a needle correctly placed for an L3 medial branch block at the junction of the L4 superior articular process and L4 transverse process. A: Right oblique view. B: Postero-anterior view.



Appendix

Critical Criteria for the Optimal Conduct of Lumbar Medial Branch Neurotomy

Patient Selection

- Anatomically accurate medial branch blocks, performed under fluoroscopic guidance [50] (Figure 1).
- Ideally complete relief of pain, but at least greater than 80% relief of pain, following medial branch blocks of the affected segment or segments [50].
- Relief confirmed by controlled blocks [50].
- Relief of pain corroborated by restoration of movements or activities previously impeded by pain [50].

Surgical Technique

- Electrodes used are of adequate size (18G–16G) [49].
- Electrodes placed accurately, parallel to the target nerve [49] (Figure 2).
- Lesions placed to cover all possible locations of the target nerve [49].

If patients are properly selected, and if correct surgical technique is used, 80% of patients treated should achieve at least 60% relief of pain for longer than 6 months [56]. If pain recurs, relief can be reinstated by repeat neurotomy [66].

Figure 2 Fluoroscopy views of electrodes correctly placed across the necks of the L4 and L5 superior articular processes for L3 and L4 medial branch neurotomy. A: Left oblique view. B: Postero-anterior view. C: Lateral view.

