LUMBAR MEDIAL BRANCH THERMAL RADIOFREQUENCY NEUROTOMY
POSITION STATEMENT OF THE SPINE INTERVENTION SOCIETY

INTRODUCTION
The lumbar zygapophysial joints are a possible source of low back pain [1-4]. These joints are innervated by the medial branches of the lumbar dorsal rami [5,6]. Pain from these joints can be diagnosed by controlled diagnostic blocks of the nerves that innervate the painful joint or joints [7-11]. Subsequently, the pain can be relieved by denervating the painful joint or joints using a procedure called lumbar medial branch thermal radiofrequency neurotomy (TRFN).

The procedure involves coagulating the medial branches that mediate the pain by placing a radiofrequency electrode parallel to each of the target nerves in multiple locations across the target zone through which the nerve runs [12]. When a radiofrequency current is delivered through the electrode, the proteins in the adjacent nerve are heated and denatured, thereby preventing nociceptive transmission along the nerve.

The paradigm of lumbar medial branch TRFN is that if pain is relieved by controlled, diagnostic blocks of the target nerves, coagulating those nerves should provide lasting relief of pain to the same degree as achieved by the diagnostic blocks. The Spine Intervention Society has published protocols for the rigorous conduct and evaluation of diagnostic medial branch blocks [13], and for the accurate and thorough performance of lumbar medial branch TRFN [14].

In accordance with these guidelines, it is the position of the Spine Intervention Society that patients selected for treatment should have experienced at least 80% relief from controlled medial branch blocks, and that treatment is conducted by placement of a large-gauge electrode parallel to the target nerve under fluoroscopic guidance.

BACKGROUND
Two benchmark studies have shown that lumbar medial branch TRFN is an effective treatment for persistent lower back pain when patients are selected for treatment on the basis of high-grade relief from controlled local anesthetic blocks and when large-gauge (16G) electrodes are used to coagulate the target nerves.

In the first study, patients were selected for treatment if they had at least 80% relief from repeated blocks [15]. Twelve months after treatment, 60% of the 15 patients had at least 80% relief of pain, and 80% had at least 60% relief. Pain relief was accompanied by reduced disability.

In the second study, patients were selected only if they experienced 100% relief from comparative blocks [16]. After treatment, complete relief of pain for at least six months, accompanied by restoration of activities of daily living and no need for continuing care for back pain, was achieved in two neighboring practices in 58% of 50 patients and 53% of 56 patients respectively. The median duration of relief was 15 months in each practice.
A randomized, placebo-controlled trial [17] used the same selection criteria and the same surgical technique as the benchmark studies, but it did not report success rates; it reported only group data. Nevertheless, those data showed that the outcomes achieved by the techniques used were superior to those of sham treatment.

**ISSUES**

Other studies [18-20], including controlled trials [21-25], have not matched the outcomes achieved in the two benchmark studies. Citing these other studies and their poor outcomes, systematic reviews have drawn and publicized negative conclusions about the effectiveness and efficacy of lumbar medial branch TRFN [26-28]. In drawing these conclusions, however, neither the systematic reviews nor the original studies gave any consideration to the poor outcomes being due to poor selection of patients or poor surgical technique or both. Yet the evidence shows that each of these factors is crucial to optimum outcome.

**EVIDENCE**

**Patient Selection**

Crucial to optimum selection of patients is the rigorous application of diagnostic blocks of the medial branches that mediate the patient’s pain. Critical variables are the number of blocks performed, the use of controls, and the degree of relief obtained [13].

Single diagnostic blocks are inadequate for selecting patients, because single blocks do not identify the 40% or so of patients whose pain is not relieved when blocks are repeated. In formal statistical terms, single blocks have a false-positive rate ranging between 25% and 41% [7-11]. Consequently, if patients are selected for treatment on the basis of single diagnostic blocks, the risk arises that 50% or more will not truly have the condition for which the treatment is designed; and their failure to respond to treatment will dilute the observed success rate.

In order to improve the validity of diagnosis, some form of controlled blocks must be used. Placebo controls constitute the optimal choice, but their use in conventional practice might not be logistically practical. A pragmatic compromise is comparative local anesthetic blocks [13]. Comparative blocks reduce the rate of false-positive responses, but they do not eliminate them. For a condition with a low prevalence, such as lumbar zygapophysial joint pain, the diagnostic confidence of conventional, comparative blocks is only the range of 30-60% [29,30]. Diagnostic confidence can be raised to 75% if comparative blocks are fully randomized; and diagnostic confidence rises to 95% if placebo controls are added [30].

The optimum criterion for a positive result of diagnostic blocks is complete relief of pain, on each occasion that the target nerves are blocked with an active agent. Lesser degrees of relief are difficult to interpret because there should be no residual pain if its source has been anesthetized. Although 50% relief of pain might be considered by some to be a sufficient criterion for a positive response, the remaining pain will not be treated by lumbar medial branch TRFN, and complete relief of pain will not ensue. As a logical rule, patients cannot expect to obtain relief after treatment that is greater than the relief that they obtain from diagnostic blocks. Consequently, for optimal outcomes from treatment, the patients selected for treatment should have high-grade relief of pain from diagnostic blocks.
Surgical Technique
Correct surgical technique is crucial for obtaining optimal outcomes. The important variables are orientation of the electrode used, the caliber of the electrode, the temperature attained, the lesion time, and the number of lesions made at each nerve [14].

Radiofrequency electrodes produce minimal lesions distal to their tip [31]. Instead, they coagulate radially around their long axis. Therefore, in order capture the target nerve in a lesion, the electrode must be placed parallel to the nerve [31]. The L1-4 medial branches and the L5 dorsal ramus cross the neck of the superior articular process in a caudal and dorsal direction at about 45° to the transverse plane of the vertebra and, in order to lie parallel to their target nerves, electrodes must be inserted along a steep trajectory from below.

If electrodes are placed perpendicular to the nerve, the risk arises of failing to incorporate the nerve in a heat lesion or incorporating the nerve only partially. Indeed, a cadaver study has shown that perpendicular placements totally miss the nerve in 30% of cases [32]. Consequently, if perpendicular placements are used, success rates will be lower (for failing to incorporate the target nerve) or relief will be only partial (for failing to fully incorporate the nerve).

Electrode placement also affects duration of effect. Placing the electrode parallel to the nerve exposes a substantial length of the nerve to a heat lesion. With a perpendicular placement, only a small length of the nerve will be exposed to heat, if at all. A cadaver study has shown that with parallel placements, the electrode is consistently parallel to the target nerve over a length of 9mm [32]. With perpendicular placements, in those cases in which the electrode actually reaches the nerve, it is parallel to the nerve for only 3.5mm. In as much as it takes a nerve longer to repair a longer length of coagulation than it does to repair a shorter length, the risk of perpendicular placements – even if the nerve is successfully coagulated – is that regeneration will occur sooner and the period of relief from pain will be shorter.

Radiofrequency electrodes have a limited range of influence. The effective range of coagulation in the radial direction is between one and two electrode-widths [31]. For small gauge electrodes to be effective, they must be placed virtually in direct contact with the nerve. A millimeter or more of displacement from the nerve places the nerve out of range of the lesion that the electrode makes. Large gauge (16G) electrodes have a larger effective range and will be effective from up to 2mm from the nerve. Consequently, placement of large gauge electrodes does not need to be as precise as when a small gauge electrode is used.

The exact location of the target nerves cannot be visualized under a fluoroscope. Moreover, the exact location of the nerve can vary from segment to segment, and from patient to patient. Consequently, there is no single location in which an electrode can be placed exactly onto the target nerve. Rather, the nerve can be interpreted as lying anywhere in a particular zone, centered on the neck of the superior articular process, but in some cases slightly higher and in other cases slightly lower. In order to guarantee capturing the target nerve thoroughly and reliably, lesions need to be placed across the entire target zone in which the nerve might be located. If large gauge electrodes are
used, this may be achieved with a single placement along a trajectory parallel to the nerve. If small gauge electrodes are used, two, three, or four placements may need to be made, depending on the size of the electrode, in order to ensure coverage of all the possible locations of the nerve. If this is not done, the risk arises of missing the nerve altogether or capturing it only partially. The correct placement of electrodes is illustrated in Figure 1.

![Figure 1](image)

**Figure 1.** 16G electrode correctly positioned adjacent and parallel to the medial branch. **A:** Declined and oblique view. **B:** Lateral view.

**COMPARATIVE OUTCOMES**

In the two benchmark studies the recommended protocols for comparative blocks [13] were rigorously followed in order to select patients, and the recommended surgical technique [14] was used. In the first study, 80% of pain was the criterion for a positive response to blocks, and this became the criterion for a successful outcome after treatment [15]. In the second study, complete relief of pain was the criterion for response to blocks, and this became the criterion for successful outcome [16]. In the first study, the successful outcome was achieved in 60% of patients for 12 months. In the second study it was achieved in 55% of patients.

These data provide proof of principle that the degree of relief obtained from diagnostic blocks can be achieved after treatment with lumbar medial branch TRFN. The success rate, however, for achieving this outcome is modest, but not negligible. Over 50% of patients achieve high-grade relief accompanied by reduction, if not elimination, of disability and no need for further health care. Unexplained is the modest success rate. The leading contender is the false-positive rate of conventional, comparative blocks.

Other studies have neither matched these outcomes, nor did they use the same, rigorous criteria for selecting patients or the same rigorous surgical technique for treatment. In these studies, it is not possible to attribute the poorer outcome to any particular factor or factors, because these studies differed either in the selection of patients or in surgical technique or both. For example, in any given study it is not possible to determine if the poor outcome was due to poor selection of patients or poor surgical technique if both
were evident. Nevertheless, clear trends can be seen.

Figure 2 summarizes the correlations between the success rate achieved by lumbar medial branch TRFN for given grades of relief from medial branch blocks. Success rates are stratified by the criterion used for a positive diagnostic block, the use of single or comparative blocks, and the use of parallel or perpendicular electrode placement to target the medial branch nerves. Not included in Figure 2 are studies that did not provide data on success rates or grades of relief [23], or studies that used outdated surgical techniques that have been proven to be totally inaccurate [33, 34].

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**Figure 2.** A matrix showing the association between the grade of relief (%) following medial branch TRFN. Success rates are stratified by the criterion used for a positive diagnostic block, the use of single or comparative blocks, and the use of parallel or perpendicular electrode placement to target the medial branch nerves. The numbers within the body of the matrix are the success rates (%) reported by the study cited for achieving the outcome corresponding to the row in which the number appears.

Figure 2 shows that complete relief of pain has rarely been achieved by studies that used perpendicular placement of electrodes. Indeed, the 6% prevalence of this outcome amounts to one patient in the literature. Otherwise, modest grades of outcome (70% or 50% relief) have been reported in a total of five patients in one study [24] and 24 in another [22].
No studies that used single blocks and parallel placement of electrodes reported high grades of relief. However, the proportions of patients who achieved at least 50% relief were appreciably larger than in the studies that used perpendicular placements.

High success rates have been reported only in studies that used comparative blocks to select patients; and those studies show an obvious correlation between the grade of outcome achieved and the grade of relief used to select patients. Intriguingly, those studies show a consistent success rate for achieving their respective outcomes. Success rates of 50% - 60% are consonant with a 50% - 60% diagnostic confidence for conventional, comparative blocks.

**DISCUSSION**

Just because a procedure carries a particular name does not mean that it was performed according to the clinical practice standard [14]. In the case of lumbar medial branch thermal radiofrequency neurotomy, there are many variants, each differing either in surgical technique or selection of patients or both. These differences have clinically significant bearing on success rates, degree of relief obtained after treatment, and duration of relief.

Under these conditions, it becomes inappropriate and illegitimate to group or compare studies that little more than carry the same name. Any grouping or comparison must take into account differences in technique or criteria for selection of patients because these differences substantially influence the success rate of the procedure.

The benchmark studies have shown that good grades of outcome can be achieved if correct selection and correct technique are used. No other treatment for any form of back pain has achieved complete relief of pain, accompanied by restoration of function, and no further need for health care. These are the outcomes that have been documented for the version of lumbar medial branch TRFN described in the Practice Guidelines of the Spine Intervention Society. No other version of the procedure has been described in detail, and no other version has been shown to achieve outcomes that match, let alone rival, those of the benchmark studies.

All other studies, including controlled trials, have achieved poor outcomes. That evidence permits the conclusion that other versions of the procedure are not effective. However, that evidence does not impugn lumbar medial branch TRFN when performed accurately and thoroughly in optimally selected patients. This distinction has recently been made clear in correspondence to journals that have published negative studies. In two instances, the authors of studies have explicitly responded that they studied how lumbar medial branch TRFN is performed in the Netherlands [35,36]. Their studies, therefore, do not apply to how the procedure is performed elsewhere.

The one limitation of the benchmark studies is their relatively modest success rates. Although high grades of relief were obtained, they occurred in only 50% - 60% of patients. This may be a reflection of the false-positive rate of comparative blocks. Greater success rates are likely to be achieved if more rigorous diagnostic block paradigms are used to select patients, such as randomized comparative blocks or placebo blocks [30], but with the risk of an elevated false negative rate. In the meantime,
the modest success rate might nonetheless be acceptable, given the high grade of relief obtained in successful cases and the relative safety of this procedure when performed according to clinical practice guidelines.

REFERENCES


