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Original Research Articles

Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand

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Abstract

Objective. This study aims to determine the effectiveness of lumbar medial branch radiofrequency neurotomy (RFN) performed by two practitioners trained according to rigorous guidelines.

Design. Prospective, outcome study of consecutive patients with chronic back pain treated in a community setting.

Interventions. A total of 106 patients, selected on the basis of complete relief of pain following controlled, diagnostic, medial branch blocks, were treated with RFN according to the guidelines of the International Spine Intervention Society.

Outcome Measures. Successful outcome was defined as complete relief of pain for at least 6 months, with complete restoration of activities of daily living, no need for any further health care, and return to work. Patients who failed to meet any of these criteria were deemed to have failed treatment.

Results. In the two practices, 58% and 53% of patients achieved a successful outcome. Relief lasted 15 months from the first RFN and 13 months for repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 17–33 months, with some 70% still having relief at follow-up.

Conclusion. Lumbar RFN can be very effective when performed in a rigorous manner in appropriately selected patients. Chronic back pain, mediated by the lumbar medial branches, can be stopped and patients fully restored to normal living, if treated with RFN.

Key Words. Chronic Pain; Back Pain; Radiofrequency; Neurotomy

Introduction

Lumbar medial branch radiofrequency neurotomy (RFN) is a treatment for a specific subgroup of patients with low back pain: those whose pain is mediated by medial branches of the lumbar dorsal rami and which ostensibly arises from the zygapophysial joint or joints innervated by these nerves [1,2]. The paradigm of lumbar RFN is that if controlled, diagnostic blocks of lumbar medial branches completely relieve the patient's pain temporarily then coagulation of those nerves should provide complete relief of pain for an extended period. Pain may recur if and when the nerves regenerate, but in that event, relief can be reinstated by repeating the neurotomy [3].

Several controlled trials have shown that the effects of lumbar RFN cannot be dismissed as placebo [4–6]. However, for various reasons, these studies did not demonstrate the optimal effectiveness of the procedure [7], nor did certain observational studies [8,9]. Some did not use controlled, diagnostic blocks to select patients [4,5,9];

some did not use optimal surgical technique [4]; some accepted patients with less than complete relief of pain following diagnostic blocks [5,8,9]; or they used patients with concomitant conditions that complicated long-term assessment [6]. To date, only one small study has established the benchmark of outcomes for lumbar RFN [10]. It showed that 60% of patients should expect at least 80% relief of pain at 12 months, or 80% of patients should expect at least 60% relief for the same period.

The present study was undertaken as a prospective audit of outcomes to determine if lumbar RFN in conventional practice achieved benchmark outcomes. In accordance with the paradigm of lumbar RFN, patients were selected for treatment only if they had complete relief of their pain followed controlled, diagnostic, medial branch blocks. Diagnostic blocks were performed using either lignocaine or bupivacaine, and the physician, the assessor of the response, and the patient were all blinded as to which local anesthetic was used. A positive response was confirmed by repeating the blocks with the local anesthetic that was not used for the first procedure. Patients selected for treatment had complete relief from pain on both occasions and were able to perform without restriction movements and activities that would usually aggravate their pain. Duration of relief following each block was not a criterion for eligibility for treatment, because the diagnostic confidence (posttest probability) of comparative blocks is only marginally superior when duration of relief is added as a criterion [11]. The exact number of patients screened with medial branch blocks is unknown because some records were lost as a result of earthquake damage but, from data that is available, it is estimated that 575 patients were screened. For outcomes of lumbar RFN to be classified as successful, pain had to be completely relieved. The results obtained provide a new benchmark for outcomes of lumbar RFN.

Methods

During 2004, two of the authors (JM and JB) were trained by the fifth author (NB) in the rigorous performance of lumbar RFN according to the standards prescribed by the International Spine Intervention Society [1,2,12]. All procedures were carried out with 16 gauge (1.6 mm diameter) Cosman RRE electrodes (Cosman Medical Inc., Burlington, MA, USA), and either 10 cm or 15 cm electrodes were used, depending on the size of the patient. Electrodes with either 5 mm or 10 mm exposed tips were placed parallel to the medial branches, across the necks of the superior articular processes, and sufficient lesions were created to cover the likely location of the nerves. All consecutive patients who underwent lumbar RFN after the period of training until December 2009 were prospectively followed. The patients were assessed and treated in each of two suburban practices conducted by practitioners with a vocational interest in musculoskeletal medicine. The outcomes were assessed, at various times after treatment, at each of the practices respectively by one of two primary care physicians (AM and BL) who were not involved in the treatment of the patients. The data collected were independently assessed and analyzed by the fifth author (NB).

Before treatment, patients recorded their pain score using a visual analog scale or verbal, numerical pain-rating scale [13–15]; they nominated four activities of daily living that were impeded by their pain and which most dearly they would want restored [16–18]; and they recorded their work status and what health care they were using for their pain. Follow-up was undertaken either during subsequent face-to-face consultations or by telephone, at which time patients were asked to report their pain scores, their activities of daily living and work status, and their use of other health care.

Outcomes were defined categorically. In order to be rated as having a successful outcome, patients had to report complete relief of pain, or at least 80% relief, for at least 6 months; restore all of their desired activities of daily living; require no other health care for their back pain; and return to work if they had not previously been working. Any other combination of response was considered a failure. Occasional exceptions were indulged. For example, return to work was excused if the patient could not work for socioeconomic reasons or for other health reasons but provided that pain was completely relieved, all activities had been restored, and no other health care was required. Patients were allowed to use analgesics if they had some other health problem that was not treated. Patients were allowed to use over-the-counter analgesics for any remnant pain, but they were deemed a failure if they required any prescription medications for their index pain.

The numbers and proportions of patients achieving various grades of outcome were tallied. The median duration (and interquartile range) of complete relief following the first RFN was calculated. Allowing for repeat treatment, the total duration of relief achieved by each patient was calculated by summing all periods of relief achieved for that patient. The median duration of cumulative relief across all patients was calculated as the median of all summed periods for individual patients. Also calculated were the median and average durations of complete relief achieved by all initial and repeat treatments.

Results

In the two practices, a total of 106 consecutive patients were treated. Their presenting demographic features are summarized in Table 1, and their presenting clinical features are shown in Table 2. The patients from the two practices were reasonably similar, demographically, although Practice B saw somewhat more patients with work-related injuries, whereas Practice A saw more patients whose back pain was attributed to other injuries such as falls, lifting, or being hit by moving objects. Clinically, the segments diagnosed and treated were similar in the two practices, but Practice A treated patients with a longer duration of pain (Table 2).

Table 1 Demographic features of patients treated with lumbar radiofrequency neurotomy

Feature	Practice A	Practice B
Gender		
Male	23	33
Female	27	23
Age (years)		
Median	50	45
Interquartile range	30–56	35–56
Range	19–77	15–80
Occupation		
Tradesman	7	15
Manual worker	5	11
Retail	2	6
Professional	6	4
Manager	3	2
Retired	2	3
Domestic duties	3	3
Student	4	2
Not recorded	11	2
Clerical	5	6
Service industry	5	2
Work status		
Working full time	15	16
Working part time	6	11
Not working	26	24
Not applicable	3	5
Injury		
Work-related	7	27
Sport	4	7
Motor vehicle accident	7	5
Other (e.g., fall, hit, lifting)	18	9
None	9	4
Not recorded	5	4

Of the patients for whom treatment was categorized as having failed, the largest subgroup were those who were outright failures; they obtained no relief of their pain (Table 3). Others were relieved of the pain for which they were treated but still had pain from other sources that impaired their recovery. Some patients were completely relieved of their pain, but for reasons not disclosed to the investigators, they were not able to restore their activities of daily living. Others were relieved of their pain and restored their activities, but the duration of relief did not last 6 months. A few patients restored their activities of daily living but did not have complete relief of their pain; variously they reported 50% or 70% relief, but not complete relief, as required by the outcome criteria. One patient died before follow-up, and two from Practice A were lost to follow-up. Two patients from that practice had complete relief of pain and had restored their activities of daily living, but they had only recently been treated and, therefore, had not reached the required 6 months duration of relief. They portend to become successful outcomes but, for present purposes they were, on technical grounds, classified as not successes.

Table 2 Presenting clinical features of patients treated with lumbar radiofrequency neurotomy

Feature	Practice A	Practice B
Duration of pain (months)		
Median	60	17
Interquartile range	36–82	10–75
Range	9–418	5–300
Numerical pain rating (0–100)		
Median	60	50
Interquartile range	50–70	40–65
Nerves treated		
T11,12	1	1
T12, L1	1	3*
T12, L1,2	0	2
L1,2,3	0	2
L2,3	4	4
L2,3,4	0	2
L3,4	11	12
L4,5	18	19*
L3,4,5	9	3
Bilateral T11,12	1	0
Bilateral T12, L1	0	2
Bilateral L1,2,3	0	1
Bilateral L2,3	0	1
Bilateral L3,4	2	1
Bilateral L4,5	3	3

* One patient was treated on separate occasions for separate complaints mediated by T12,L1 and L4,5.

Table 3 Outcomes of patients treated with lumbar radiofrequency neurotomy

Outcome		Practice A	Practice B
Failure	Outright; no relief	9	13
	Other pain	4	6*
	Pain relieved; activities not restored	0	2
	Pain recurred, before 6 months	2	0
	Not complete relief of pain	2	5
	Deceased	0	1
	Lost to follow-up	2	0
	Not yet reached 6 months	2	0
Success	Complete relief of pain	29	30
	Activities restored		
	No other health care	58%	53%
	Return to work	(44–72)	(40–66)

* Includes the patient treated successfully for pain at T12,L1 but without relief at L4,5.

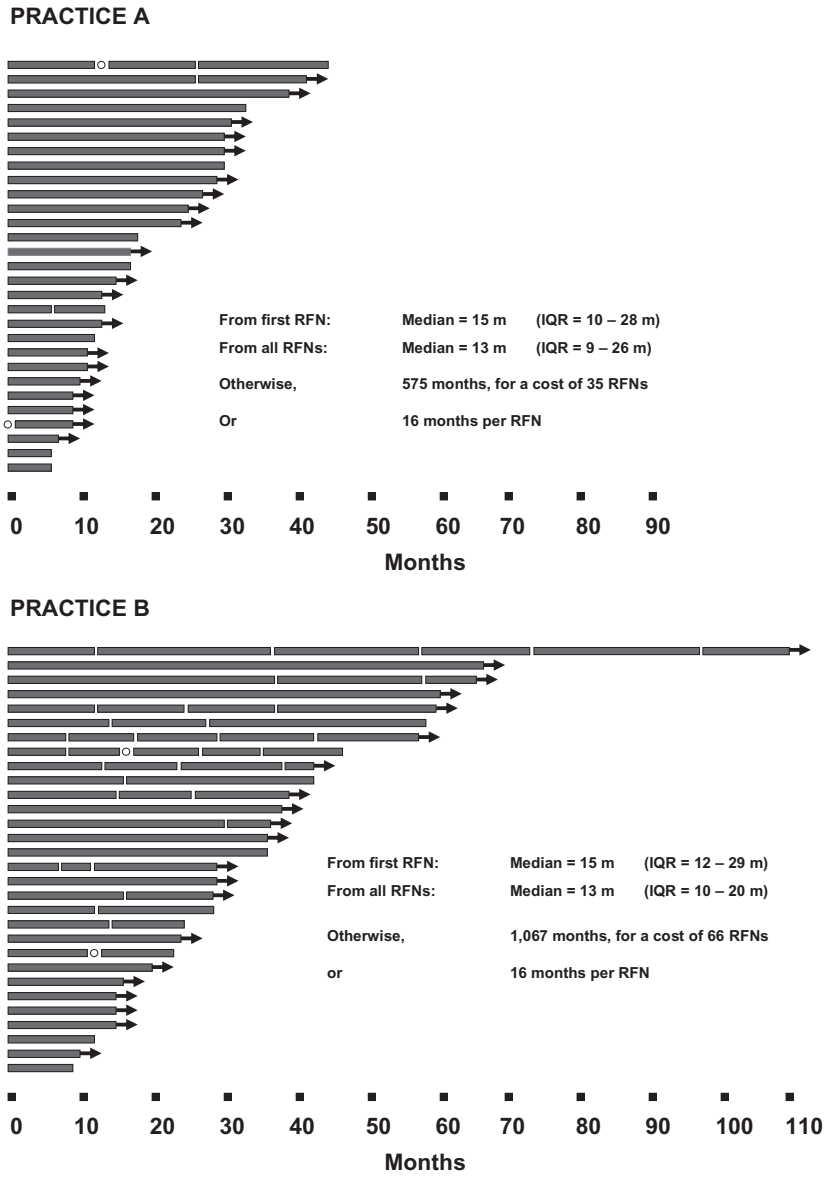

Figure 1 Duration of relief reported by patients treated with lumbar radiofrequency neurotomy. Each line represents one patient. Each bar indicates the duration of relief following a single treatment. Interruptions indicate that relief ceased, followed by repeat treatment. Arrowheads indicate that complete relief was continuing at the time of follow-up. Circles indicate an RFN that was not successful. The insets summarize the statistical parameters of each set of outcomes. IQR = interquartile range; RFN = radiofrequency neurotomy.

All other patients satisfied the criteria for successful outcome. They had complete relief of pain for at least 6 months; they restored their activities of daily living; they required no other health care (apart from over-the-counter medications, if at all); and they returned to work. Concessions applied to only five patients. In Practice A, one patient reported 90% relief of pain, and in Practice B, one reported 90%, two reported 95%, and one reported 80% relief, but all of these patients completely restored their activities of daily living, required no other health care, returned to work, and were very satisfied with their outcome. All other patients had complete relief of pain. The proportions of patients who achieved successful outcomes in the two practices were similar, (58%, 53%) and were not significantly different statistically.

Among the patients with a successful outcome, some requested, and underwent, repeat treatment; others are awaiting repeat treatment, or have not requested it. Figure 1 shows the number of treatments undertaken to achieve and maintain complete relief of pain over an extended period.

The median duration of complete relief of pain following the first successful RFN was 15 months in Practice A (interquartile range: 10–28 months) and 15 months (12–29 months) in Practice B. Practice A performed few repeat treatments and achieved an aggregate of 575 months of complete relief of pain, in 29 patients, using 35 treatments, which amounts to a median duration of cumulative relief of 17 (11–30) months, and a median

duration of 13 months per treatment, or an average of 16 months per treatment. Practice B performed more repeat procedures, and thereby kept patients free of pain for a longer period. It achieved an aggregate of 1,067 months of complete relief in 30 patients, using 66 treatments, which amounts to a median duration of cumulative relief of 33 (19–46) months, and median duration of 13 months per treatment, or an average of 16 months per treatment. In both practices, two-thirds of patients successfully treated still had ongoing relief of pain at the time of follow-up. So, the figures above constitute worst case values for the duration of relief achieved by RFN.

Discussion

Remarkable in the results of the present study are the consistencies between the operators in the two practices. Each practice obtained virtually identical success rates, and the median durations of relief, achieved by the first RFN, and by all RFNs, were essentially the same. This consistency confers internal validity to the study and predicates external validity. Both operators used the same diagnostic protocol and the same operative technique [1,2]. Others who do so should expect the same outcomes.

The outcome measures used in the present study were unusual but deliberately so. The paradigm of lumbar RFN predicts that if patients achieve complete relief of pain following controlled, diagnostic blocks, they should achieve complete relief following RFN. Therefore, complete relief of pain was adopted as the cardinal criterion for successful outcome. This had to be accompanied by complete restoration of activities in daily living, and no need for any other health care. These latter measures were used not only to corroborate the relief of pain but also to indicate that lumbar RFN is a restorative treatment. Without any other intervention, lumbar RFN completely relieves over 50% of patients of their pain and restores them to normal life. No other treatment for low back pain has ever been shown to achieve such outcomes.

Previous studies of lumbar RFN used generous definitions of success. They have reported 20–70% of patients achieving at least 50% relief of pain for 3, 6, 12, or 24 months [4–6,8,9], but they did not report the proportions of patients achieving complete relief of pain, which implies that few, if any, patients did so. The results of the present study are distinctly different, both in terms of the number of patients who achieved complete relief of pain and the duration over which that relief lasted. The possible reasons for these differences bear consideration.

In the present study, patients were selected for treatment if their pain was relieved by controlled, comparative local anesthetic blocks [11,19,20]. Others do not use controlled blocks.

Patients were selected for treatment only if their pain was completely relieved by diagnostic blocks. Others accept 50% relief as constituting a positive response.

Rigorous and meticulous operative technique was used. Large 16G electrodes were used. Others use 21G or 22G electrodes, which can fail to incorporate the target nerve into a lesion [12]. Multiple lesions were made in order to encompass all possible locations of the target nerve [1,12]. Others use an expeditious, single lesion, which can fail to incorporate the nerve, or can fail to incorporate an adequate length of nerve [1,12]. The electrodes were placed parallel to the target nerve. Others use perpendicular placements, which can fail to coagulate the nerve, or might coagulate an insufficient length of nerve [1,12]. No personal or arbitrary variant of lumbar RFN has been shown to be as effective as the method prescribed by the International Spine Intervention Society and used in the present study [12].

New Zealand patients were unambiguous about their outcomes. Either the procedure worked or it did not. Only six of the 106 patients treated reported only partial relief of pain; the majority clearly had no relief or complete relief of their pain. This contrasts with outcomes reported in North America, where partial relief of pain appears to be reported more commonly. This difference might be due to the lesser selection criteria used in North America, or there might be psychosocial differences between New Zealand patients and North American patients in the way that they respond to treatment.

Of some concern is why the success rate in the present study was only 53–58%. The paradigm of lumbar RFN expects a far greater success rate. Several explanations apply.

First, among the failures were patients whose pain was not completely relieved by diagnostic blocks. For example, their pain scores fell from 50 to 5, but not to zero. The operator nevertheless optimistically ventured to perform RFN, which did not succeed. All patients who did have a successful outcome from RFN had complete relief of pain from their diagnostic blocks. This suggests that complete relief of pain following diagnostic blocks is mandatory for complete relief of pain following RFN.

Second, the responses of several patients were confounded by other sources of pain. As a result, although their index pain was completely relieved, the persistence of the other pain prevented them from restoring the activities of daily living. Thus, RFN was intrinsically successful but could not be shown to be so given the criteria for success that were set a priori. A morality debate arises as to whether or not patients should be relieved of some of their pain when they suffer from other sources of pain that prevent their complete rehabilitation.

Enigmatic are those patients who reported complete relief of pain during diagnostic blocks but did not restore their activities of daily living following apparently successful RFN. This combination suggests a false-positive

response both to treatment and to the original, diagnostic blocks.

Comparative local anesthetic blocks are not an ideal diagnostic test. Although their sensitivity is high, their specificity is modest (65%) [11,19,20]. Therefore, it is possible that some the patients treated had false-positive responses to diagnostic blocks. Either this possibility can be accepted, together with the attendant failure rate of treatment, or it can be reduced, and the success rate of RFN improved, by using placebo-controlled blocks to select patients for treatment [11].

Notwithstanding these limitations, the results of the present study demonstrate that lumbar RFN can be a very successful treatment. The patients in the study were not "highly selected" in the sense that prognostically they were somehow destined to recover. They were highly selected for having a particular form of back pain, diagnosed by controlled, medial branch blocks. In such patients, the present study shows that lumbar RFN is not curative but can be highly restorative. The initial yield of RFN of about 10% is reasonable, and success can be maintained by repeating the procedure, over multiple years. For patients with this form of back pain, no other treatment has been shown to be effective; no other treatment eliminates pain, restores function, and eliminates the need for other health care. There is no alternative or rival treatment for these patients.

The present study echoes and extends the benchmark originally set by Dreyfuss et al. [10]. They showed that 60% of patients could expect at least 80% relief at 12 months. The present study shows that a similar proportion maintain complete relief of pain for over 12 months, and for much longer if RFN is repeated. This benchmark is achieved by using rigorous protocols for diagnosis [2] and for treatment [1]. It raises serious questions about operators who claim that 50% relief at 3 months with a 20% reduction in use of opioids constitutes a success [21]. Complete relief of pain with no need for other health care is the benchmark for successful lumbar RFN.

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