

PERCUTANEOUS RADIO-FREQUENCY NEUROTOMY FOR CHRONIC CERVICAL ZYGAPOPHYSEAL-JOINT PAIN

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ABSTRACT

Background Chronic pain in the cervical zygapophyseal joints is a common problem after whiplash injury, but treatment is difficult. Percutaneous radio-frequency neurotomy can relieve the pain by denaturing the nerves innervating the painful joint, but the efficacy of this treatment has not been established.

Methods In a randomized, double-blind trial, we compared percutaneous radio-frequency neurotomy in which multiple lesions were made and the temperature of the electrode making the lesions was raised to 80°C with a control treatment using an identical procedure except that the radio-frequency current was not turned on. We studied 24 patients (9 men and 15 women; mean age, 43 years) who had pain in one or more cervical zygapophyseal joints after an automobile accident (median duration of pain, 34 months). The source of their pain had been identified with the use of double-blind, placebo-controlled local anesthesia. Twelve patients received each treatment. The patients were followed by telephone interviews and clinic visits until they reported that their pain had returned to 50 percent of the preoperative level.

Results The median time that elapsed before the pain returned to at least 50 percent of the preoperative level was 263 days in the active-treatment group and 8 days in the control group ($P=0.04$). At 27 weeks, seven patients in the active-treatment group and one patient in the control group were free of pain. Five patients in the active-treatment group had numbness in the territory of the treated nerves, but none considered it troubling.

Conclusions In patients with chronic cervical zygapophyseal-joint pain confirmed with double-blind, placebo-controlled local anesthesia, percutaneous radio-frequency neurotomy with multiple lesions of target nerves can provide lasting relief. (N Engl J Med 1996;335:1721-6.)

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CHRONIC neck pain after whiplash injury has defied diagnosis and treatment. The Quebec Task Force on Whiplash-Associated Disorders found almost no literature to substantiate the use of commonly practiced treatments for this condition.¹ In about half of patients with chronic neck pain of this type, the pain originates in the cervical zygapophyseal joints.^{2,3} It cannot be diagnosed clinically or radiographically but can be identified by using local anesthesia to block the nerves supplying the painful joint.²⁻⁶ However,

treatment has remained problematic. A controlled trial showed that intraarticular injections of corticosteroids offer no particular benefit.⁷ The only other treatment that has been advocated is percutaneous radio-frequency neurotomy.⁸⁻¹⁴ This operation offers temporary relief of pain by denaturing the nerves that innervate the painful joint. The pain returns when the axons regenerate, but relief can be reinstated by repeating the procedure.

Previous studies of percutaneous radio-frequency neurotomy have been hampered by poor selection of patients, inaccurate techniques, poor outcome measures, and the lack of controls.^{15,16} We report the results of a controlled trial of the procedure.

METHODS**Study Patients**

We conducted this study at the Cervical Spine Research Unit, a tertiary referral center at the Mater Misericordiae Hospital in Newcastle, Australia, that treats only patients with neck pain lasting more than three months after the motor vehicle accident to which the pain is attributed. To enter the study, the patients had to have already been assessed by a specialist, had to have tried conventional therapy without success, and had to have been referred by a medical practitioner. Conventional therapy typically involved using some combination of analgesics, nonsteroidal antiinflammatory drugs, opioids, physiotherapy, traction, acupuncture, chiropractic, transcutaneous electrical nerve stimulation, locally applied heat, and exercise.

The study patients were selected from among patients whose cervical zygapophyseal-joint pain had been confirmed with the use of local anesthetic blocks at either the unit or a private radiology practice in Newcastle. Patients with C2-3 zygapophyseal-joint pain were excluded, because the pilot study had shown that treatment at this level by radio-frequency neurotomy was technically difficult.¹⁶ Patients with painful C3-4 to C6-7 zygapophyseal joints were included. To be eligible for the trial, patients had to have their perception of pain confirmed by placebo-controlled, diagnostic blocks.

For such confirmation to be made, each patient underwent three blocks of the medial branches of the two dorsal rami supplying the putatively symptomatic joint. On the first occasion, one of two local anesthetics (2 percent lidocaine or 0.5 percent bupivacaine) was randomly used. On the second occasion, either normal saline or the other local anesthetic was used. On the third occasion, the agent that was not used in the second test (that is, normal saline or the remaining anesthetic) was used. All the blocks were performed under strict double-blind conditions, with the use of a lateral approach guided by an image intensifier, and with 0.5 ml of the assigned agent.^{3,6} The patient's perception of

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TABLE 1. BASE-LINE CHARACTERISTICS OF THE 24 PATIENTS WITH CHRONIC CERVICAL ZYGAPOPHYSEAL-JOINT PAIN.*

CHARACTERISTIC	ACTIVE-TREATMENT GROUP (N=12)	CONTROL GROUP (N=12)
Age — yr	44±12	43±12
Sex — M/F	5/7	4/8
Employed — no. of patients	4	7
Involved in litigation — no. of patients	4	10†
Months of pain — median (interquartile range)	44 (23–94)	34 (25–92)
Symptomatic joints — no. of patients		
C3–4	3	3
C4–5	1	0
C5–6	4	4
C6–7	1	1
C2–3 and ipsilateral C4–5‡	1	1
C2–3 and contralateral C5–6‡	1	1
C2–3 and ipsilateral C4–5‡ and C5–6‡	0	1
Bilateral C2–3 and C5–6 and contralateral C6–7‡	0	1
C3–4‡§	1	0
Visual-analogue scale — score	40±15	47±18
McGill Pain Questionnaire — score		
Total word count	14±5	12±5
Pain rating	37±19	32±16
SCL-90-R score — median (interquartile range)		
Somatization	0.8 (0.6–1.6)	0.7 (0.3–1.5)
Obsessive-compulsive disorder	0.7 (0.5–1.1)	0.8 (0.2–2.1)
Interpersonal hypersensitivity	0.6 (0.4–0.9)	0.4 (0.1–1.4)
Depression	0.8 (0.3–1.5)	1.3 (0.2–2.6)
Anxiety	0.4 (0.2–0.7)	0.5 (0.2–1.1)
Hostility	0.3 (0.2–0.8)	0.2 (0.2–0.6)
Phobic anxiety	0.1 (0.0–0.4)	0.1 (0.0–0.3)
Paranoid ideation	0.1 (0.0–0.3)	0.3 (0.0–1.1)
Psychotic symptoms	0.1 (0.0–0.3)	0.1 (0.0–0.8)

*Plus-minus values are means ±SD.

†P=0.04 for the comparison with the active-treatment group, by Fisher's exact test.

‡This joint was selected to undergo treatment (active or control).

§This patient also had lower pain not of zygapophyseal-joint origin.

pain was considered to be confirmed only if the patient had complete relief of pain each time a local anesthetic was used, but no relief when normal saline was used.

On the basis of data from a pilot study,¹⁶ our calculations of power indicated that a sample containing not less than 12 patients in each group would be required.¹⁷ The first 24 patients who met the criteria for the study were enrolled. Approval to conduct the study was granted by the ethics committees of the University of Newcastle and the Hunter Area Health Service. All the participants gave written informed consent.

Base-Line Assessment

Before surgery, each patient rated his or her typical level of pain over the preceding two weeks on a 100-mm visual-analogue scale on which the values ranged from 0 (no pain) to 100 (“the worst pain I could imagine”).¹⁸ The patients also completed the McGill Pain Questionnaire, in which they selected the words that best described their pain from a series of words in various categories. As many as 20 words could be selected, and the severity of pain could be gauged reliably by counting the words chosen and totaling the values assigned to them in rank order.^{19,20} Each patient

was asked to list the four activities of daily living that had been affected by the joint pain that he or she would most want to see restored by successful treatment. The activities mentioned most often were returning to work, doing housework (in particular, hanging out laundry, vacuuming, and gardening), driving or traveling long distances, playing sports, having sex, and lifting children or caring for them. A psychologist administered the SCL-90-R, a validated, 90-item checklist that measures psychological distress on subscales corresponding to nine psychological symptoms (listed in Table 1).²¹

Operative Technique

The technical details of the operative procedure have been described elsewhere.¹⁶ A 10-cm, 22-gauge electrode with a 4-mm exposed tip was introduced percutaneously, under fluoroscopic control, so that it contacted each of the two nerves supplying the painful joint. For each nerve the electrode was introduced twice; once along a parasagittal path to reach the nerve as it crossed the lateral aspect of the ipsisegmental articular pillar, and again at a 30-degree angle to the sagittal plane in order to reach the nerve over the anterolateral aspect of the pillar (Fig. 1). At each location two or three lesions were made, to accommodate possible variation in the course of the nerve.¹⁶ Lateral and anteroposterior radiographs were obtained of every placement of the electrode during which a lesion was made (Fig. 2).

The patients were assigned on the basis of a computer-generated schedule of random numbers to receive either active treatment, in which the temperature of the electrode tip was raised to 80°C for 90 seconds, or control treatment, in which the temperature was maintained at 37°C. In every other respect the procedures used in the two groups were identical.

One surgeon performed all the operations and made all the preoperative and postoperative assessments. Another operator controlled the radio-frequency generator. The device was masked so that the surgeon had no way of determining the temperature of the electrode tip. Regional anesthesia was used, with 2 ml of 0.5 percent bupivacaine infiltrating the territory around each target nerve. Each operation lasted approximately three hours. Neither the patient nor the surgeon knew the patient's treatment assignment (the temperature of the electrode used) until the completion of the trial.

Postoperative Assessment

Remaining unaware of the treatment assignments, the surgeon assessed each patient. All the patients were contacted twice by telephone after their operations, at three to five days and at two to three weeks, and they were formally interviewed at three months. During that interview, the patients completed the visual-analogue scale and the McGill Pain Questionnaire. They indicated which of the four activities of daily living they had listed earlier had been restored, and they were asked, “Is your usual pain present?” and “Do you require further treatment for your pain?” Yes-or-no answers to these questions were recorded. The duration of their relief from pain was recorded, as were any side effects or complications. A neurologic examination was performed to document any sensation of numbness.

After the three-month interview, patients who reported either no relief or an early return of their pain were offered “escape” therapy in the form of percutaneous radio-frequency neurotomy with the active treatment. Patients decided about reoperation only after all outcome measures had been recorded in the controlled trial and without knowing whether they had received active or control treatment during that trial. Those whose relief continued for three months postoperatively were asked to telephone the study investigators as soon as their pain returned to at least 50 percent of the preoperative level. In addition, they were formally interviewed at 12 months and once a year thereafter. They were also seen in person at any time if complications were suspected and were seen promptly if their preoperative level of pain returned.

The treatment was considered to have failed if a patient report-

ed no relief of the accustomed pain immediately after the operation or when the pain returned to at least 50 percent of its preoperative level. This cutoff level was chosen because it represented a more stringent threshold than waiting for the pain to return completely, and because a previous study had shown that patients can reliably determine that 50 percent of pain has returned.⁷

For the treatment to be considered successful, a patient had to report complete relief from the pain for which he or she was treated. (In addition to neck pain, some patients had headache or back pain for which they were not treated.) The relief had to be corroborated by a score of 0 to 5 of a possible 100 on the visual-analogue scale, a word count of three or less on the McGill Pain Questionnaire, and the restoration of all four activities of daily living that the patient had listed before the operation. To the questions "Is your usual pain present?" and "Do you require further treatment?" the patient had to answer in the negative. For those with pain other than neck pain, the requirement that the activities of daily living had to be restored was waived if the untreated pain interfered with those activities.

Statistical Analysis

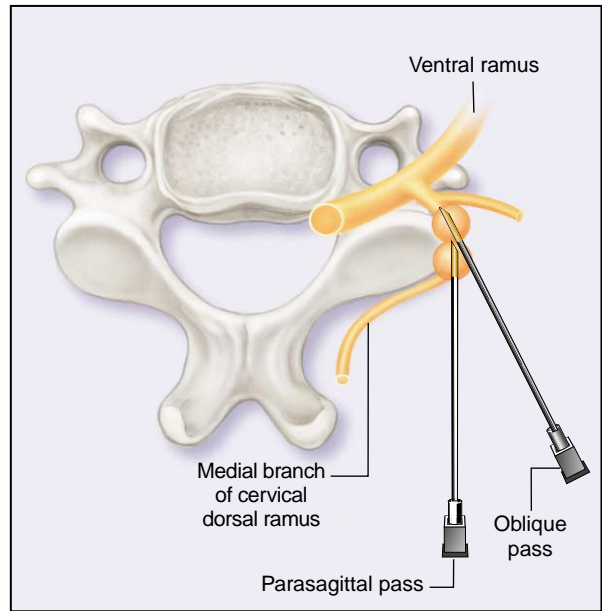
Once all the subjects had completed the three-month assessment, the randomization code was broken in a limited fashion. One member of the research team remained unaware of the treatment assignments in order to monitor the long-term progress of the patients who had continuing relief of pain. Kaplan-Meier survival curves were constructed for both treatment groups, and the Mantel-Haenszel test²² was used to calculate the significance of the difference between the curves.

RESULTS

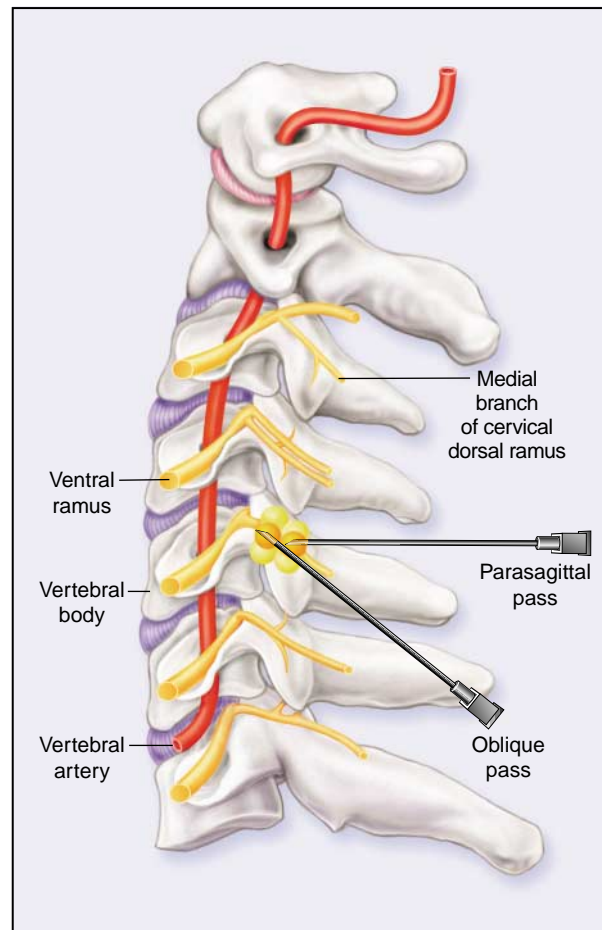
Study Patients

Fifty-four patients were screened in order to identify 24 patients who met the criteria for inclusion in the study (Table 1). The other 30 patients were excluded either because they did not have relief of their pain when the confirmatory diagnostic blocks were used or because they had responses when the blocks involving saline were used. These patients were referred back to their medical practitioners for treatment of their symptoms.

None of the 24 study patients had signs of radiculopathy, and no features diagnostic of such disease were seen on plain radiographs. In 17 patients the neck pain was predominantly unilateral, stemming from one zygapophyseal joint; the other 7 (3 in the active-treatment group and 4 in the control group) had more than one source of pain. Table 1 shows the combinations of symptomatic joints and the joints treated. The patients with pain from more than one source could clearly distinguish the pain for which



A



B

Figure 1. The Use of Electrodes to Coagulate a Medial Branch of a Cervical Dorsal Ramus.

Panel A shows a cross section through the C5 vertebra. An oblique pass is used to reach the nerve over the anterolateral aspect of the articular pillar. A parasagittal pass is used to reach the nerve over the lateral aspect of the pillar. With each pass, lesions are placed at, above, and below the cephalocaudal center of the pillar (Panel B).

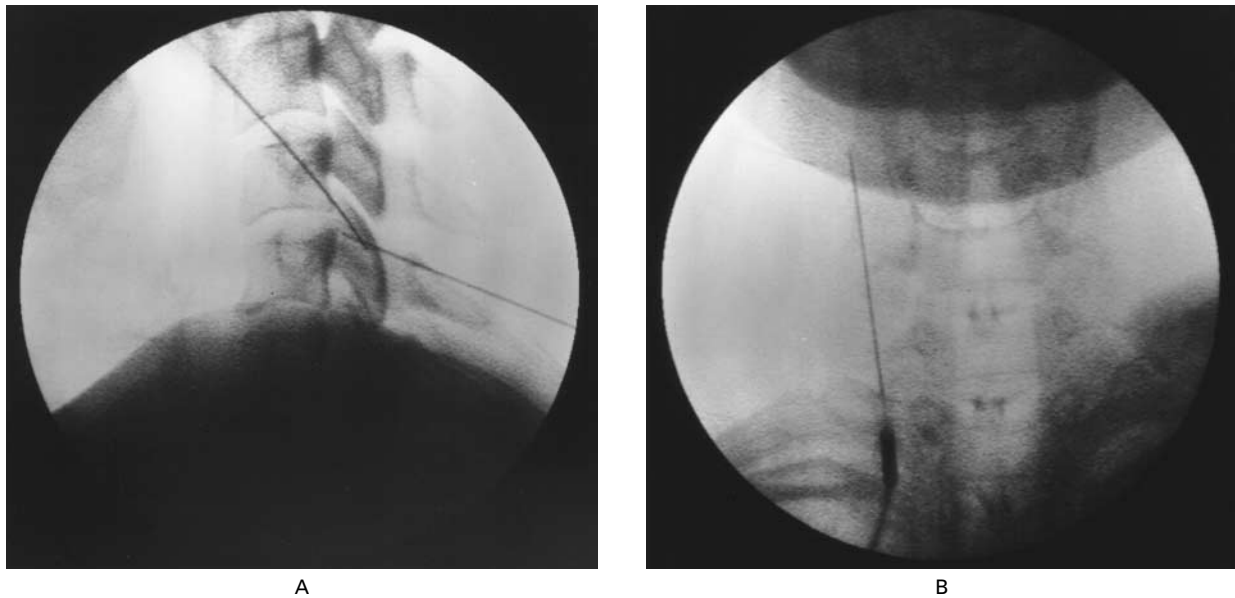


Figure 2. Lateral (Panel A) and Anteroposterior (Panel B) Radiographs Showing the Insertion of the Electrode along a Parasagittal Plane to Make Lesions over the Lateral Aspect of the Articular Pillar.

they were treated from the pain for which no treatment was offered.

There were no significant differences between groups with respect to age, sex, employment status, duration of pain, joints treated, or base-line scores on the visual-analogue scale, the McGill Pain Questionnaire, and the SCL-90-R. However, after randomization, the control group included more patients engaged in ongoing litigation related to their motor vehicle accidents. No patient was lost to follow-up.

Surgery

During their operations, all the patients had adequate regional anesthesia, so no sensations of heat or pain compromised the blinding of the study. The surgeon could not determine which patients received the active treatment, either during the operation or subsequently. No intraoperative complications occurred.

Postoperative Assessment

Postoperatively, all the patients could clearly distinguish their accustomed pain from any postoperative pain caused by the electrodes and needles that penetrated their neck muscles. Pain associated with the procedure lasted a median of 3.5 days (interquartile range, 1 to 16) in the control group and 13.5 days (interquartile range, 6 to 15) in the active-treatment group ($P=0.26$ by the Mann-Whitney U test). No patient in the control group had numbness that lasted longer than the patient's regional anesthesia. Five patients in the active-treatment group

had numbness or dysesthesias in the cutaneous territory of the coagulated nerves (C3-4 in three patients and C4-5 and C5-6 in one patient each), but none rated these sensory changes as troublesome or requiring treatment. One patient in the active-treatment group had a psoriatic rash starting at the skin incision (Köbner's phenomenon) one week after the operation.

Six patients in the control group and three in the active-treatment group had a return of their accustomed pain in the period immediately after the operation. By 27 weeks, one patient in the control group and seven in the active-treatment group remained free of pain (Fig. 3). The median time to the return of at least 50 percent of the preoperative level of pain was 263 days in the active-treatment group and 8 days in the placebo group ($P=0.04$ by the Mantel-Haenszel test). Patients engaged in litigation were no more likely to report relief from pain than nonlitigants in either group.

Two patients in the active-treatment group who had no relief from their pain were subsequently found to have pain from spinal segments adjacent to those treated, as if the treatment of the initial pain had uncovered a secondary source of pain. One such patient, who had incomplete relief after a C5-6 neurotomy, had pain mediated by the medial branch of C7. The other had pain from C2-3 in addition to C3-4.

Second Procedures

Five patients in each study group underwent second procedures. Three patients in the active-treatment group, who had less than three months' relief

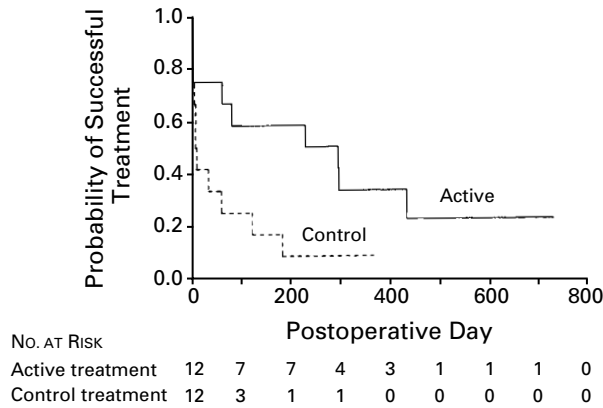


Figure 3. Kaplan–Meier Curves of the Probability of Successful Treatment in Patients Receiving Active or Control Treatment. During active treatment, the tip of the electrode was heated to 80°C, whereas during control treatment it remained at a temperature of 37°C. The number of patients at risk for treatment failure at each time point is shown below the graph.

after the first procedure, did not have relief of their pain after the second procedure. One patient in the control group had no relief after either the initial procedure (without active treatment) or the “escape” procedure (with active treatment). As of January 1996, the other six patients (two in the active-treatment group and four in the control group) had complete relief lasting a median of 253 days (interquartile range, 186 to 397).

DISCUSSION

We confirmed the presence of chronic cervical zygapophyseal-joint pain preoperatively by using rigorous criteria.⁶ The control procedures mimicked the active procedures in every respect, except that the radio-frequency current was not turned on. Treatment was considered successful only if there was complete relief of pain, as corroborated by the visual-analogue scale and the McGill Pain Questionnaire, by the patient’s report that he or she perceived no pain and needed no further treatment, and by the restoration of desired activities of daily living. With this definition of success, percutaneous radio-frequency neurotomy proved to be clinically and statistically more efficacious than the control procedure. Moreover, there was complete relief of pain in some patients whose symptoms had been present for more than 12 months. Such patients are ordinarily extremely unlikely to recover spontaneously or to respond to conventional therapy.^{1,23}

The sample we studied was small because, from an ethical viewpoint, subjecting patients to a sham operation that lasted three hours and involved risks of infection, exposure to radiation, and postoperative pain made it imperative to recruit as few patients as

necessary. Although a higher proportion of patients involved in litigation were assigned to the control group, the response to treatment was not affected.

Neither the patients nor the assessor came to know the patients’ study assignments, and therefore the study was not compromised. Although numbness occurred only in patients in the active-treatment group, all the patients were warned, when they gave informed consent, to expect such side effects. Placebo theory predicts that even patients receiving a control treatment can have side effects that are expected with active treatment.²⁴ Numbness, therefore, did not necessarily indicate that a patient had undergone an active procedure.

The significant rate of response to the control treatment, even among patients who had been tested with placebo-controlled diagnostic blocks to confirm their perceptions of pain, is a sobering reminder of the complex and inconstant dynamics of placebo phenomena. Patients may have a placebo response on one occasion but not another.²⁵⁻²⁷ Moreover, the more invasive an intervention, the more powerful is its placebo effect.²⁸ Thus, a patient who does not have a placebo response with diagnostic blocks may nonetheless have such a response after surgery.

Although we have shown that percutaneous radio-frequency neurotomy is significantly more efficacious than placebo, problems with the procedure remain. Despite apparently clear diagnoses, patients may obtain no relief even after more than one neurotomy. Others can have additional pain revealed after their original, dominant pain is treated. On the other hand, patients who have relief for a limited time after an initial operation sometimes have relief again after a second procedure, and for a longer time. Technical precision and adequate denaturation of the target nerves are paramount during surgery.

Our results apply only to patients responsive to double-blind, placebo-controlled, diagnostic blocks whose treatment involves multiple lesions of the target nerves. The results cannot be generalized to apply to patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique.

The purpose of this study was not to determine the duration of relief after percutaneous radio-frequency neurotomy; rather it was to evaluate the procedure by comparing it with a control procedure. We found that radio-frequency neurotomy provided lasting, complete relief, but only in a moderate proportion of patients. Nevertheless, as shown in this study and previously,¹⁶ such relief can last for months to over a year, and if pain recurs the relief can usually be reinstated by repeating the procedure. By appraising the technique further and continuing to monitor our experience, we will attempt to improve the rate and duration of success.

Supported by a grant from the Motor Accidents Authority of New South Wales.

We are indebted to the staff members of the radiology department and the recovery ward, Mater Misericordiae Hospital, Waratah, Australia, and to Drs. Dear and Maindonald of the Department of Statistics, University of Newcastle, for their help with the data analysis.

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