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Percutaneous Lumbar Zygapophysial (Facet) Joint Neurotomy Using Radiofrequency Current, in the Management of Chronic Low Back Pain

A Randomized Double-Blind Trial

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Study Design. A randomized controlled study of percutaneous radiofrequency neurotomy was conducted in 40 patients with chronic low back pain (20 active and 20 controls).

Objective. The aim of the study was to evaluate the possible beneficial effect of percutaneous radiofrequency zygapophysial joint neurotomy in reducing pain and physical impairment in patients with pain from the lumbar zygapophysial joints, selected after repeated diagnostic blocks.

Summary of Background Data. Facet or zygapophysial joint pain may be one of the causes of chronic low back pain and may be treated by a percutaneous radiofrequency denervation. Patients may possibly be identified by a positive diagnostic block. These blocks need to be repeated as false positive responses to single blocks occur.

In all previous studies patients treated with radiofrequency denervation have been selected after single diagnostic blocks resulting in a varying degree of relief.

Methods. All patients were examined by an orthopedic surgeon before and 6 months after the treatment (sham or active). Inclusion criteria were 3 separate positive facet blocks. Denervation was achieved by multiple lesions at each level in an effort to provide effective denervation.

Results. The active treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacro-iliac joint test. Pre operative sensory deficit and weak or absent ankle reflex normalized ($P < 0.01$) and ($P < 0.05$), respectively. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain.

The improvement seen in the active group was significantly greater then that seen in the placebo group with regard to all the above-mentioned variables.

None of our patients had any complication other than transient postoperative pain that was easily managed.

Conclusion. Our study indicates that radiofrequency facet denervation is not a placebo and could be used in the treatment of carefully selected patients with chronic low back pain.

Key words: percutaneous neurotomy, Zygapophysial joint, facet joint, low back pain, randomized controlled trial, radiofrequency, denervation. **Spine 2008;33:1291–1297**

Most patients who develop low back pain recover within 3 months but the few who have persistent pain represent a large (often hidden) burden of morbidity.[1] A possible cause of chronicity is pain emanating from the zygapophysial (or facet) joints.[2] There are no features, on history or examination, whereby lumbar zygapophysial joint pain can be diagnosed clinically[3–5] nor can it be diagnosed by CT.[6] Diagnostic blocks are the only means by which the source of a patient's pain can be traced to their zygapophysial joints.[7,8] Single diagnostic blocks have been shown to be associated with a high false-positive rate.[8] To reduce the likelihood of false-positive responses, repeated blocks are required. Comparative local anesthetic blocks using Lidocaine or Bupivacaine are a suitable form of control.[9,10]

In patients whose pain is relieved by such blocks radiofrequency medial branch neurotomy may be considered. This procedure coagulates the nerves that mediate the patient's pain and thereby provides pain relief.[11]

Two systematic reviews[12,13] have identified 3 trials that have tested lumbar medial branch neurotomy[14–16] on the basis of which they concluded that there was moderate[12] or conflicting[13] evidence of efficacy. Since then a fourth trial[17] has been published. In none of these trials were the patients selected on the basis of controlled (repeated) diagnostic blocks. Therefore, patients who did not have lumbar zygapophysial joint pain could have been included. More particularly, it has been pointed out that none of the trials used an adequate denervation technique.[18] The fourth trial mentioned above did not differ in diagnostic or radiofrequency technique from van Kleef's study. Either, or both, of these factors could have reduced the apparent efficacy of the procedure.[11,19]

There is therefore insufficient evidence for the efficacy of lumbar medial branch neurotomy. However, a descriptive study[20] has indicated how effective the procedure can be if patients are selected using controlled diagnostic blocks and if anatomically accurate technique is used. Sixty percent of patients enjoy at least 80% relief from their pain, sustained at 12 months and 80% enjoy at least 60% relief. The selection criteria in this study were very stringent and as far as possible, only patients with limited and clear cut facet joint pain were included.

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The primary aim of the present prospective randomized study was to compare the outcome of RF neurotomy *versus* sham surgery in patients with chronic facet joint pain that had been resistant to all previous treatments. It constitutes the first randomized trial to have used controlled (*repeated*) diagnostic blocks for patient selection and *multiple* lesions along the nerve.

■ Materials and Methods

The study was approved by the ethics committee at the University hospital. No financial contribution or sponsorship from industry or any other source was received.

The population from which the study sample was drawn were adult patients with continuous low back pain of at least 2 years duration, who had not responded to previous treatment. Excluded were patients with pregnancy, coagulopathies, malignancy, infections, mental handicap, and psychiatric disorders; patients with a motor deficit or any other indication for surgical treatment; and patients who lived too far away to be able to participate in follow-up.

To be eligible, patients had to be able to identify at least one component of their pain which could be attributed to one or more lumbar zygapophysial joints. Such patients had to have paravertebral tenderness, and obtain at least 80% relief of pain following controlled, medial branch blocks. Patient's were not required to report relief of all of their pain, but had to be confident that a recognizable component, or region, of their pain was consistently relieved by the blocks.

After clinical and radiologic assessment, using MRI or CT, 376 patients underwent screening medial branch blocks using 1 mL bupivacaine 0.5% at each of the of the standard target points[21] at segmental levels corresponding to sites of paravertebral tenderness. Screening blocks were negative in 115 patients. The remaining 261 patients obtained at least 80% relief of at least a component of their pain, and were invited to participate in the study. They were informed that they could withdraw from the study at any time, and receive the active treatment.

All 261patients proceeded to controlled blocks using lidocaine and bupivacaine. For each block, they were blinded as to the agent used. They recorded the degree and duration of pain relief, using visual analog scores (VAS) hourly for 6 hours, and were assessed the next day. Forty-five patients were negative to controlled blocks. A further 105 patients had prolonged responses to blocks and were not considered eligible for RF treatment. Another 53 patients lived too far away to guarantee follow-up, and 18 declined to participate in the treatment phase of the study.

The remaining 40 patients formed the study sample. Each was able to identify a component of their pain that was consistently relieved by medial branch block, with longer-lasting relief when bupivacaine was used. They were randomized into an active group and a placebo group using a computer-generated randomization schedule. They remained blinded to their assignment throughout the study period. The active treatment group were 6 men and 14 women, with a mean age of 56 years (range, 36–79), who had a mean duration of pain of 11 years (range, 2–27). The placebo group was 9 men and 11 women, with a mean age of 53 years (range, 37–76), who had a mean duration of pain of 12 years (range, 2–51).

All procedures were performed by the same operator (S.N.) and all the preoperative baseline and postop outcome measurements at 6 month follow-up were performed by the same orthopedic surgeon (K.P.) at another institution.

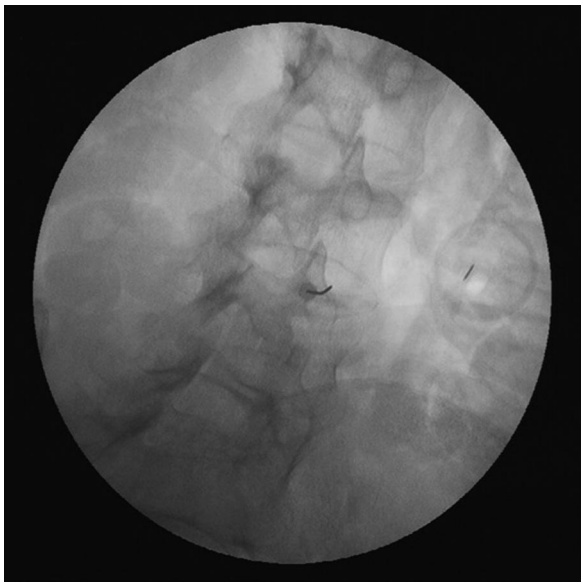

Figure 1. 'Tunnel' view L4 Transverse process with the tip of the electrode in the lateral part of the target area. Lesions are also performed after repositioning medially along the curvature towards the articular process.

Radiofrequency Technique

Both procedures (active and placebo) were identical except no current was used in the placebo group and the electrode tip remained at body temperature. The RF machine was placed behind the operator (S.N.) who was unaware of the current level that was operated by another person (C.N.) who was the only one of the workers who was aware of the randomization and this was never discussed between the coworkers. The procedure was performed in the prone position using a Radionics radiofrequency generator, model RFG 3B (Radionics Inc., Burlington, MA).

The lumbar spine was visualized and the radiograph beam was adjusted to come from a postero-lateral aspect to get the best possible view of the curvature of the medial part of the upper border of the transverse process where it ascends to become the ventro-lateral border of the superior articular process. In patients with a hypertrophic superior articular process due to arthritic changes greater lateral rotation was required. The C-arm was then declined caudad so that the direction of the radiograph beam was from below looking upwards and somewhat medially along the groove in which the medial branch lies.

The skin points were then marked and anesthetized with 1% lidocaine.

A 22 SWG SMK C15 cannula with a 5 mm active tip was introduced along the direction of the radiograph beam, in the so-called "tunnel technique" until bone contact was made with the lower part of the transverse process (L5 and higher). The cannula was then rotated so that the bevel was against the bone allowing the needle to slide up in the groove maintaining contact with the bone surface till the tip was at the upper border and in the center of the curvature formed by the upper border of the transverse process ascending to form the lateral border of the articular process. The position was checked in the tunnel view (Figure 1), the postero-lateral view (Figure 2) as well as a cephalad view (Figure 3). The lateral view (Figure 4) confirmed

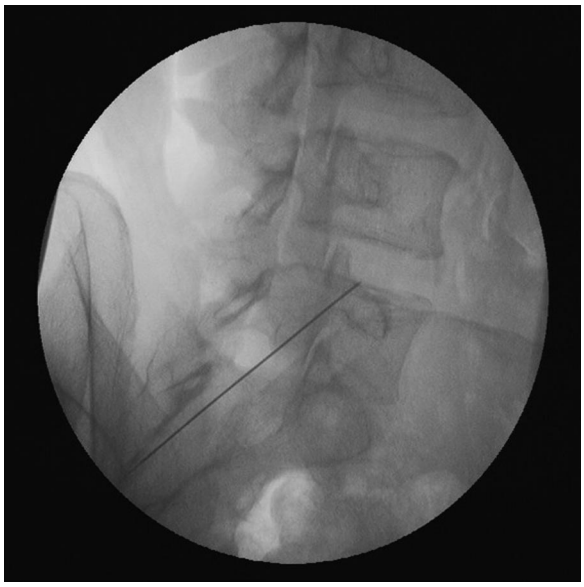

Figure 2. Postlat. view L5 Transverse process. Adjacent lesions are performed medially.

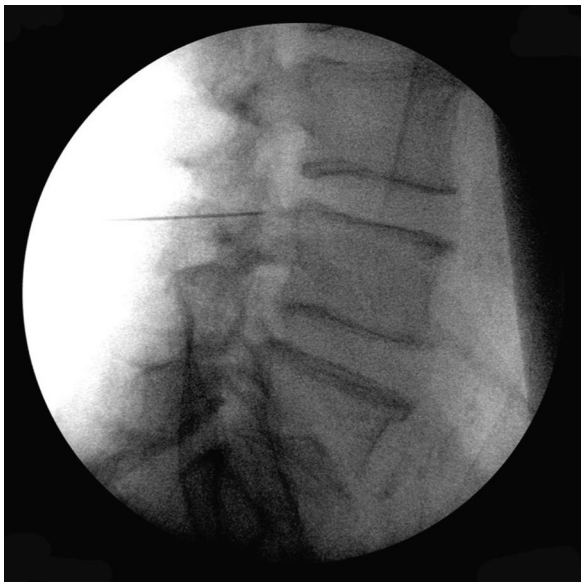

Figure 4. Lateral view. The tip of the electrode does not protrude any closer to the foramen avoiding risking damaging the nerve root.

that the cannula was not too far in, encroaching on the foramen.

At the S1 level (L5 dorsal ramus) a similar view was maintained to lay the cannula in the groove between the lower part of the lateral aspect of the superior articular process of S1 and the upper surface of the ala of the sacrum. The tunnel view confirmed the position in the groove (Figure 5). The forward advance was checked rotating the C-arm to look from a more lateral aspect to visualize the anterior border of the superior articular process of S1 (Figure 6), and then from a more cephalad aspect to visualize the point of the needle in relation to the anterior border of the ala of the sacrum (Figure 7). Figures 1 to 4 show the electrode tip in the lateral most of the 3 lesion positions.

Once the cannula had been placed, 2 mL of bupivacaine (0.5%) was injected through the cannula to anesthetize the target nerve and its surrounding tissues. The thermistor probe was inserted and a 60 second lesion was performed maintaining a temperature of 85°C. The cannula was then withdrawn 5 mm and another lesion made. To accommodate possible variations in location of the target nerve, 4 more lesions were performed just lateral and just medial to the first 2 lesions.

All patients were re-examined by the same orthopedic surgeon (K.P.) 6 months after the procedure (active or sham) with the objective of seeing if there was a difference between the 2 groups regarding pain reduction and physical impairment.

Outcome Measures

Primary outcome measures were global perception of improvement, relief of generalized pain, low back pain, and pain in the

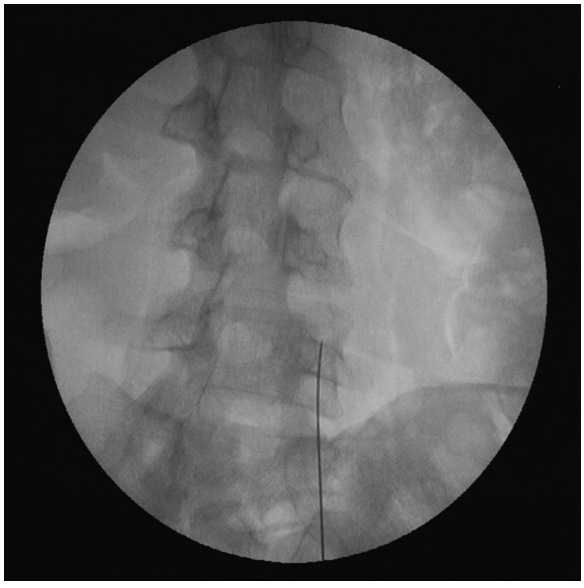

Figure 3. 'Cephalad' view L5 Transverse process of the lateralmost lesion.

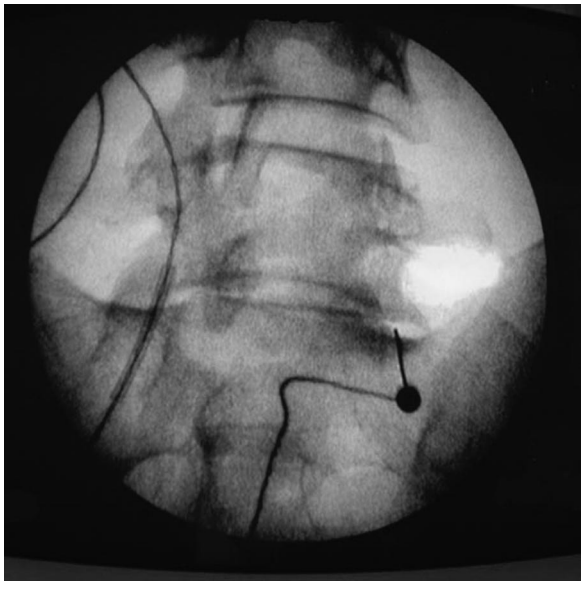

Figure 5. Tunnel view S1 Articular process with the tip of the electrode on the ala of the sacrum just lateral to the articular process.

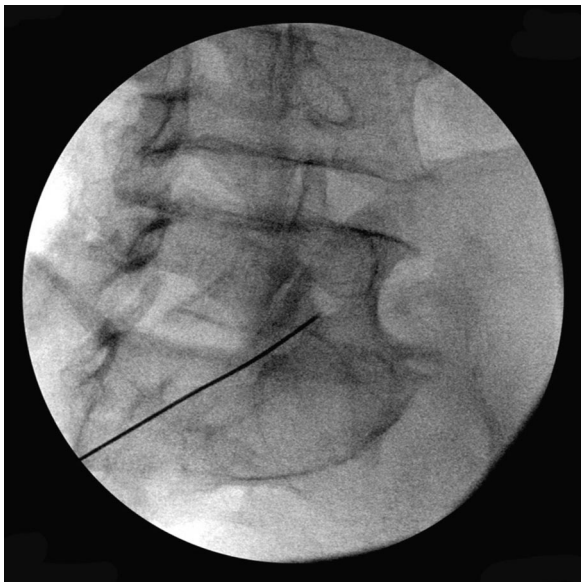

Figure 6. Postlat. view S1 Articular process showing the tip of the electrode at the anterior border avoiding deeper penetration so as not risking damage to the anterior ramus.

lower limb. Global improvement was the patients own subjective assessment on a 6-point scale. Generalized pain, back and leg pain was assessed using a visual analogue scale.

Secondary outcomes were range of motion of the lumbar spine, hip movement, quality of life variables, and clinical signs (Table 1). Range of movement was measured in degrees, using a goniometer. Quality of life variables were scored by the patient on a 6-point scale. Clinical signs were registered as present or absent.

Statistics

A multivariate analysis of *variance* (MANOVA) was used to compare the *difference* in the RF group (before and after active intervention) with the *difference* in the placebo group (before and after sham intervention). A 2-tailed significance level of less than 0.05 was considered statistically significant. Fisher's exact test was used for some analyses and student *t* test for others. The SPSS 11.0 program was used for the analyses.

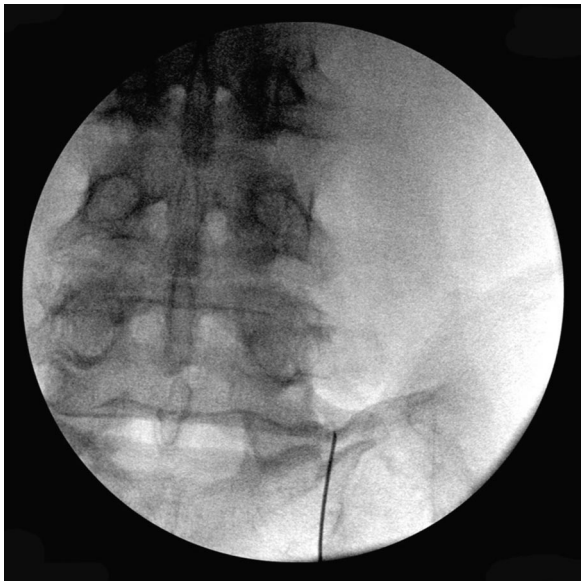

Figure 7. 'Cephalad' view S1 Articular process, further confirming a safe position (not too deep). Further lesions are performed medially on the lower lateral surface of the articular process.

■ Results

All 40 patients completed the study. After randomization, there were no differences between the 2 groups with respect to gender, age, or duration of pain. However, the patients in the RF treatment group had significantly more generalized pain, low back pain, and referred pain to the leg when compared with the placebo group (Table 1). All hip movements were also worse in the group that was randomized to active treatment (Table 1).

In terms of the patients' own global assessment, the active treatment group improved by 1.1 U ($P < 0.001$) whereas the placebo group improved by only 0.3 U ($P = 0.055$). The difference in improvement between groups was 0.8 U ($P = 0.004$).

Generalized pain was reduced in the active group by 1.9 U on an 11-point VAS scale ($P = 0.002$) but by only 0.4 U in the placebo group ($P = 0.29$). The difference in reduction between groups was 1.55 ($P = 0.02$) (Table 1).

Back pain was reduced in the active treatment group by 2.1 U ($P = 0.004$), and referred pain to the leg was reduced by 1.6 ($P = 0.016$). In the placebo group, the corresponding figures were 0.7 U ($P = 0.13$) and 0.13 ($P = 0.31$). The differences in reduction between groups were statistically significant ($P = 0.004$).

In various secondary outcome measures, the active treatment group exhibited improvements that were statistically and clinically greater than those in the placebo group. These measures included: back movement and hip movement (Table 1), quality of life variables (Table 1), the sacroiliac joint test, paravertebral tenderness, and tactile sensory deficit (Table 2). In the active treatment group, analgesic requirement was reduced by 1.4 U on a 6-point scale ($P < 0.001$), while the placebo group improved by 0.6 U ($P = 0.024$). The difference in improvement favored the active treatment group ($P = 0.04$) (Table 1).

■ Discussion

The patients that were included in this study had had severe disabling pain for a long time, and had been resistant to all previous therapies. Widespread pain, bilateral pain, and other components, such as radicular pain, coexisted in many patients. No single treatment is likely to be able eliminate all pain in such patients. However, these patients were all able to identify a particular component of their pain that was relieved by medial branch blocks, under controlled conditions, and which could be targeted for treatment by RF neurotomy.

Under those conditions, RF treatment provided significantly greater relief of low back pain and leg pain than

Table 1. Variables 1–27, (R = right, L = left)

Physical Examination	Variable	Active Group			Placebo Group			Diff. btw. diff, act. & plac.	95% Confidence Interval		Sign.
		Baseline	Primary Outcome	Difference	Baseline	Primary Outcome	Difference		Lower Bound	Upper Bound	
Back movement	Flexion	56.25	71.00	14.75	61.25	65.00	4.75	10.0	−0.25	20.25	0.056
	Extension	7.00	15.00	8.00	11.00	11.00	0.00	8.0	3.88	12.1	<0.001
	Side flexion left	16.50	23.50	7.00	16.25	20.50	4.25	2.75	−3.5	9.0	0.38
	Side flexion right	17.75	25.00	7.25	18.50	19.25	0.75	6.5	−0.1	13.1	0.053
Hip movement	Adduction R	20.75	27.75	7.00	23.50	22.75	−0.75	7.75	3.1	12.4	0.002
	Adduction L	20.25	27.25	7.00	25.50	23.50	−2.00	9.0	3.7	14.3	0.002
	Abduction R	36.25	41.00	4.75	41.50	42.50	1.00	3.75	−1.1	8.6	0.13
	Abduction L	36.75	43.50	6.75	40.00	40.00	0.00	6.75	0.42	13.1	0.037
	Inward rotation R	17.75	26.25	8.50	23.25	25.00	1.75	6.75	0.5	13.0	0.035
	Inward rotation L	17.75	25.25	7.50	23.75	24.75	1.00	6.5	−1.0	14.0	0.09
	Outward rotation R	26.00	37.75	11.75	30.50	34.00	3.50	8.25	0.16	16.3	0.046
	Outward rotation L	25.75	38.00	12.25	32.75	33.50	0.75	11.5	2.9	20.1	0.010
Generalized pain	VAS (0–10)	6.03	4.10	−1.93	4.35	3.98	−0.38	−1.9	−3.0	−0.8	0.02
Back pain	VAS (0–10)	5.98	3.88	−2.1	4.38	3.68	−0.7	−1.4	−3.0	0.17	0.08
Leg pain	VAS (0–10)	4.33	2.73	−1.6	2.68	2.55	−0.13	−1.5	−2.9	−0.03	0.046
Quality of life variables											
Analgesic consumption	6 Point scale	3.95	2.55	−1.40	3.80	3.20	−0.60	−0.8	−1.56	−0.04	0.04
Personal hygiene	6 Point scale	2.25	1.45	−0.80	1.35	1.40	0.05	−0.85	−1.4	−0.28	0.005
Walking	6 Point scale	2.60	2.20	−0.40	2.45	2.05	−0.40	0.00	−0.6	0.6	1.0
Sitting	6 Point scale	3.85	3.10	−0.75	3.50	3.35	−0.15	−0.6	−1.2	−0.03	0.04
Sleep	6 Point scale	3.25	2.60	−0.65	3.45	3.10	−0.35	−0.3	−0.8	0.2	0.2
Traveling	6 Point scale	2.50	2.25	−0.25	2.05	2.10	−0.05	−0.3	−0.7	0.12	0.16
Social life	6 Point scale	3.35	2.50	−0.85	2.80	2.60	−0.20	−0.65	−1.3	0.04	0.06
Standing	6 Point scale	3.90	2.90	−1.00	3.55	3.30	−0.25	−0.75	−1.5	−0.03	0.04
Leisure	6 Point scale	3.80	2.95	−0.85	3.50	3.15	−0.35	−0.5	−1.1	0.1	0.1
Sex	6 Point scale	3.00	2.60	−0.40	2.60	2.25	−0.35	−0.05	−0.7	0.57	0.8
Work	6 Point scale	4.75	3.15	−1.60	3.70	3.55	−0.15	−1.45	−2.4	−0.5	0.004
Subjective global assessment	6 Point scale	3.85	2.75	−1.1	3.35	3.05	−0.30	−0.8	−1.3	−0.3	0.004

did placebo treatment. This relief was accompanied by significantly greater improvements in paravertebral tenderness, various movements, quality of life, and use of analgesics. Most of these improvements are readily attributed to the relief of pain. Others, such as normalization of sacro-iliac signs, sensory deficits, and reflexes, are intriguing, but our study was not designed to determine the mechanism of these changes. The study was designed only to test active RF treatment against placebo. In that respect, the results show that the improvements obtained from RF treatment cannot be attributed to placebo effects.

The study was deliberately not designed to compare long-term efficacy, as demanded by Niemisto *et al.*[13] Patients who received placebo treatment could not be left untreated for longer than 6 months. The present study expressly assessed whether the immediate and short-term effects of RF treatment were placebo effects or not. The study showed that they were not. Given that result, long-term efficacy can be studied more easily by audit alone.

For patients like those in the present study, RF neurotomy is not a total treatment. It provided relief for only one component of the patients' pain. Nevertheless, this relief was substantial and considered worthwhile by the patients who received it. None of the patients had any complications, and the procedure was well-tolerated. If necessary, the treatment can be repeated to reinstate relief if it wanes.[27] We submit, therefore, that RF neurotomy can be used successfully, and on the basis of evidence, as a compliment to other interventions in patients with otherwise complex low back pain.

■ Conclusion

We feel there is a place for radiofrequency facet denervation in the treatment of carefully selected patients along side other treatment methods. It is worth remembering that this is a minimally invasive procedure where the morbidity is low in expert hands when the procedure is properly performed,[28] none of our patients had any complication other than transient post-operative pain that was easily managed. It is a procedure that is well tolerated, can be performed as an outpatient procedure and can provide lasting relief even in patients with long standing pain. We do not consider it to be a permanent solution but do not feel that there is any problem in repeating the procedure, should it be necessary.

It must be said, however, that the success rate depends on the ability of the operator to place the electrodes with

Table 2. Variables 28–38, With Significant *P*-values

		Active Group			Placebo Group		
Physical Examination	Variables	Baseline	Primary Outcome	Difference	Baseline	Primary Outcome	Difference
Lasegue test SLR	Yes	0	0	0	0	0	0
	No	20	20	0	20	20	0
Crossed lasegue test	Yes	3	1	−2	5	4	−1
	No	17	19	2	15	16	1
Sacro-Iliac test	Yes	16	6*	−10	15	10	−5
	No	4	14*	10	5	10	5
Signs of trochanteritis	Yes	8	7	−1	10	10	0
	No	12	13	1	10	10	0
Para vertebral tenderness (Facet joint test)	Yes	13	5†	−8	11	10	−1
	No	7	15†	8	9	10	1
Inter-spinal tenderness	Yes	16	Í0	−6	14	8	−6
	No	4	10	6	6	12	6
Dermatomal sensations affected	Yes	16	9	−7	9	9	0
	No	4	11†	7	11	11	0
Knee reflex right	Normal	14	18	4	18	16	−2
	Weak	5	1	−4	2	4	2
	Absent	1	1	0	0	0	0
Knee reflex left	Normal	14	18	4	19	18	−1
	Weak	5	0	−5	1	2	1
	Absent	1	2	1	0	0	0
Ankle reflex right	Normal	10	16	6	14	14	0
	Weak	4	3	−1	3	3	0
	Absent	6	1	−5	3	3	0
Ankle reflex left	Normal	10	16	6	14	15	1
	Weak	5	3	−2	2	2	0
	Absent	5	1	−4	4	3	−1

*$P < 0.01$, †$P < 0.05$.

precision. Developing expertise in the use of fluoroscopy and correct interpretation of the images is essential.

■ Key Points

- Establishing and treating a cause of low back pain.
- Description of the technique of facet joint denervation.
- Demonstrate the efficacy and safety of the technique in carefully selected patients.

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