

Randomized Trial of Radiofrequency Lumbar Facet Denervation for Chronic Low Back Pain

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Study Design. A prospective double-blind randomized trial in 31 patients.

Objectives. To assess the clinical efficacy of percutaneous radiofrequency denervation of the lumbar zygapophysial joints in reducing pain, functional disability, and physical impairment in patients with back pain originating from the lumbar zygapophysial joints.

Summary of Background Data. Chronic low back pain is a major health problem in the industrialized world. A treatment option is percutaneous radiofrequency denervation of the lumbar zygapophysial joints. Its clinical efficacy has never been formally tested in a controlled trial.

Methods. Thirty-one patients with a history of at least 1 year of chronic low back pain were selected on the basis of a positive response to a diagnostic nerve blockade and subsequently randomly assigned to one of two treatment groups. Each patient in the radiofrequency treatment group (15 patients) received an 80 C radiofrequency lesion of the dorsal ramus of the segmental nerve roots L3, L4, and L5. Patients in the control group ($n = 16$) underwent the same procedure but without use of a radiofrequency current. Both the treating physician and the patients were blinded to the group assignment. Before treatment, physical impairment, rating of pain, the degree of disability, and quality of life were assessed by a blinded investigator.

Results. Eight weeks after treatment, there were 10 success patients in the radiofrequency group ($n = 15$) and 6 in the sham group ($n = 16$). The unadjusted odds ratio was 3.3 ($P = 0.05$, not significant), and the adjusted odds ratio was 4.8 ($P < 0.05$, significant). The differences in effect on the visual analog scale scores, global perceived effect, and the Oswestry disability scale were statistically significant. Three, 6, and 12 months after treatment, there were significantly more success patients in the radiofrequency group compared with the sham group.

Conclusions. Radiofrequency lumbar zygapophysial joint denervation results in a significant alleviation of pain and functional disability in a select group of patients with chronic low back pain, both on a short-term and a long-term basis. [Key words: lumbar zygapophysial joint denervation, radiofrequency, randomized trial] *Spine* 1999;24:1937-1942

A major proportion of the adult population has acute low back pain at some stage of life.⁵¹ A specific cause is found in only a few patients.⁴⁹ In most patients, symptoms tend to resolve without any specific treatment, but in 8-12% of patients, chronic low back pain syndrome develops and becomes a major source of disability.^{14,51} The cause of this chronic pain syndrome remains obscure; a specific therapy is not available.

Historically, the lumbar zygapophysial joints have been implicated in low back pain syndromes.^{1,2,12,16,17,37} The estimated prevalence of lumbar zygapophysial joint pain among patients with low back pain ranges from 15% to 40%.^{43,44} The source of innervation of the lumbar zygapophysial joints has been described in detail.³⁻⁵ Several studies have been reported that were designed to reduce possible nociceptive input from the lumbar facet joints.^{7,8,21,26,39} Shealy was the first to use radiofrequency current for denervation of the lumbar zygapophysial joints.⁴⁶ Since then, the technique has been modified and widely used with varying results.^{13,15,18,19,22,24,27-30,35,36,40,45,47,48} At present, only one randomized controlled trial of the effects of radiofrequency lumbar zygapophysial joint denervation for chronic low back pain has been published.¹⁵ This study reported only modest outcomes and its results remain inconclusive, because it used the invalidated Shealy technique and such important aspects as the effects on physical impairment and disability were not investigated.

In the current study, we tested the hypothesis that percutaneous radiofrequency lumbar zygapophysial joint denervation could be more effective than placebo block in reducing pain, functional disability, and physical impairment in patients with back pain originating from the lumbar zygapophysial joints. To this end a double-blind, randomized, controlled trial was performed to examine the results of radiofrequency denervation for lumbar zygapophysial joint pain, using pain scores, disability, physical impairment, and quality of life as outcome measures.

■ Methods

Patient Selection. The study was conducted in the Pain Management and Research Centre, University Hospital Maastricht, The Netherlands. It was approved by the University Hospital Medical Ethics Review Board, and all patients gave written, informed consent before entering the trial. The study group was recruited from patients with chronic nonspecific low back pain who had been referred by various medical specialists (neu-

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rologists, neurosurgeons, orthopedic surgeons) and who had had extensive diagnostic assessment. In addition, all patients had had physical therapy, manipulation, transcutaneous electrical nerve stimulation, and medication. This conservative therapy had not provided satisfactory pain relief. Before inclusion in the study, the patients were examined by a staff neurologist (WW) to exclude clinical lumbar radiculopathies and other neurologic abnormalities.

Patients were selected for a diagnostic nerve block of the posterior primary ramus of the segmental nerves L3, L4, and L5 (patients with unilateral symptoms underwent unilateral blocks, and patients with bilateral pain underwent bilateral diagnostic blocks) provided the following criteria were met: age between 20 and 60 years, chronic low back pain of more than 12 months' duration, an initial mean visual analog scale (VAS) score of more than 4 or a VAS high score of more than 7, conservative therapy attempted without success, and absence of any neurologic deficit by routine neurologic examination.

Excluded from the study were patients who had had previous back surgery and patients with a known specific cause of low back pain (*i.e.*, signs of herniation, spondylolisthesis, spondylosis ankylopoetica, spinal stenosis, extensive multilevel spondylosis, malignancy, infection, or trauma). Patients with diabetes mellitus and patients with more than one pain syndrome were also excluded.

Diagnostic Nerve Blocks. Patients fulfilling the above criteria underwent a diagnostic dorsal ramus nerve block with a local anesthetic solution. Using fluoroscopic guidance 22-gauge needles were directed to the standard posterior primary ramus targets (medial branch), as described.⁴ For diagnostic blocks L3, L4, and L5 were selected. These were chosen because L4–L5 and L5–S1 are most frequently involved in lumbar zygapophysial joint pain.^{32,44} In view of the innervation of the zygapophysial joint⁴ from at least two spinal levels, the diagnostic nerve blocks were performed at two levels for each joint (*e.g.*, L3 and L4 for the L4–L5 facet joint). This strategy of multiple diagnostic blocks in one session was chosen to minimize patient discomfort.

Lidocaine (1%; 0.75 mL) was injected slowly at each target. Patients were instructed to score the effect on their pain on a four-step Likert scale (0–30% pain relief was considered no pain relief; 30–50% was defined as moderate, 50–80% pain relief as good, and 80–100% as free of pain) 30 minutes after the blocks were administered. Those patients who had at least 50% pain relief were eligible to enter the study.

Treatment. The trial was a double-blind, randomized study. Patients who fulfilled the study criteria and who had consented to participate were divided in two strata, depending on the result of the diagnostic nerve block (good relief or free of pain) and with help of a computer program were randomized in blocks of two into two treatment groups: Group I was treated with a 60-second radiofrequency lesion of 80 C of the medial branch of the posterior primary ramus of the segmental nerves L3–L5 on one or on both sides. In Group II, electrodes were introduced as in Group I, but no radiofrequency lesion was made. Apart from the running radiofrequency current the therapeutic procedure was identical to the one applied in Group I.

The patient and operator were blinded to the study procedure performed. The patients were not aware of the type of treatment received, and the treating physician left the operating room after inserting the electrodes and injecting the local anes-

thetic solution. Stimulation criteria such as motor stimulation of the multifidus muscle or any pain perceived by the patient during the procedure were recorded by an independent investigator. The radiofrequency generator was operated by this investigator.

Technique of Radiofrequency Percutaneous Facet Denervation. With the patient prone on the operating table, a C-arm image intensifier (BV 25; Philips, Eindhoven, Netherlands) was positioned in a slightly (10–15°) oblique position, until the junction between the superior border of the transverse process and the lateral aspect of the superior articular process was clearly visible at L4 and L5 and the junction of the ala of the sacrum and the articular process of the sacrum at S1. In these locations, the medial branches of the posterior primary rami of the L3, L4, and L5 segmental nerves run in a posterior direction on their way to the groove on the posterior aspect of the base of the transverse process or of the sacral ala, respectively. Entry points were marked overlying these junctions, and the area was disinfected and draped. A 22 SWG SMK C10 (Radionics, Inc., Burlington, MA) cannula with a 5-mm active tip was introduced at each entry point in the direction of the x-rays. Each of the three cannulas was carefully advanced, with the proper direction checked after each step until the tip made contact with bone at the posterior aspect of the junction. The cannula was then redirected in a slightly more cephalad and lateral direction until contact with bone was lost (Figure 1). The position of the cannula was checked on the lateral fluoroscopic projection, and the depth was adjusted until the tip of the cannula was at the level of a line connecting the posterior aspects of the intervertebral foramen (Figure 2).

The stylet of the cannula was replaced by a radiofrequency probe, and electrostimulation at 2 Hz was performed to confirm the proximity of the electrode to the dorsal ramus and to exclude inadvertent proximity to the exiting segmental nerve. When muscle contractions in the multifidus muscle did not occur below 1.0 V, the cannula was repositioned. Eventually the stimulation threshold was below 1.0 V (preferably below 0.5 V) in this series of patients. The absence of contractions of leg muscles was verified at 1.5 V. Once the position of the electrode was satisfactory, the radiofrequency probe was removed from the cannula, and 1 ml 1% lignocaine was injected through each cannula. The radiofrequency probe was reinserted, and a 60-second 80 C lesion was made using a radiofrequency lesion generator (model 3C Radionics, Burlington, MA).

Evaluation. Data were obtained by an investigator (H MV) blinded to the subject's condition. Rating of pain was assessed by averaging three daily measurements of the VAS, ranging from 0 to 10 cm, for 4 days.²⁰ In these 4 days, the minimum and maximum scores were reported as VAS-low and VAS-high, respectively. Global perceived effect was scored by the patient on a 7-point scale (ranging from much worse, -3; to 0, no change; to total pain relief, +3). Before treatment, there was an objective clinical evaluation of physical impairment according to Waddell and Main⁵² and Waddell and Turk.⁵³ Scores obtained from patients ranged from zero (indicating no impairment) to 7 (maximum impairment). Analgesic intake, (predominantly nonsteroidal antiinflammatory drugs) was simultaneously monitored with the VAS scores in the same diary. Disability was assessed by the Oswestry disability scale,¹¹ which is a questionnaire containing 60 items on limitations in

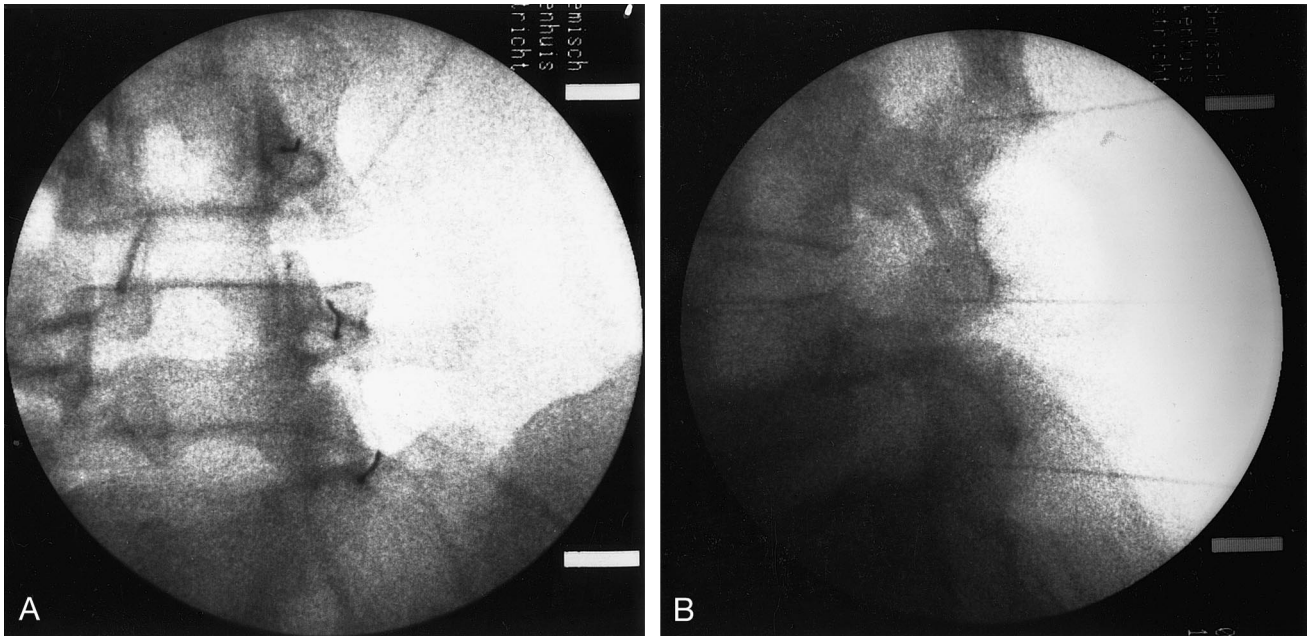


Figure 1. Electrode positioning during lumbar zygapophysial joint denervation. **A**, Anteroposterior view, slightly oblique projection. **B**, Transverse projection.

various daily activities. The Dartmouth COOP Functional Health Assessment Charts/World Organization of Primary Care Physicians (WONCA) (COOP/WONCA) chart,^{31,41} a quality of life questionnaire, divided into seven items to be scored on a 5-point scale.

The patients were assessed before treatment and 8 weeks after treatment. Only in patients with at least a 2-points reduc-

tion on the VAS scale (VAS-mean or VAS-high) and at least a 50% pain reduction on global perceived effect was the treatment scored as a success. In all other patients, the treatment was classified as a failure. Assessment was conducted at 3, 6, and 12 months after the procedure. At the time of this re-evaluation, patients were asked whether they were satisfied with the effect of the treatment. If not, the treatment was scored as a failure, and the patient was taken out of the study for ethical reasons, so that the patient could receive other therapies, such as clinical rehabilitation. If a patient reported at least 50% pain relief, he or she remained in the study.

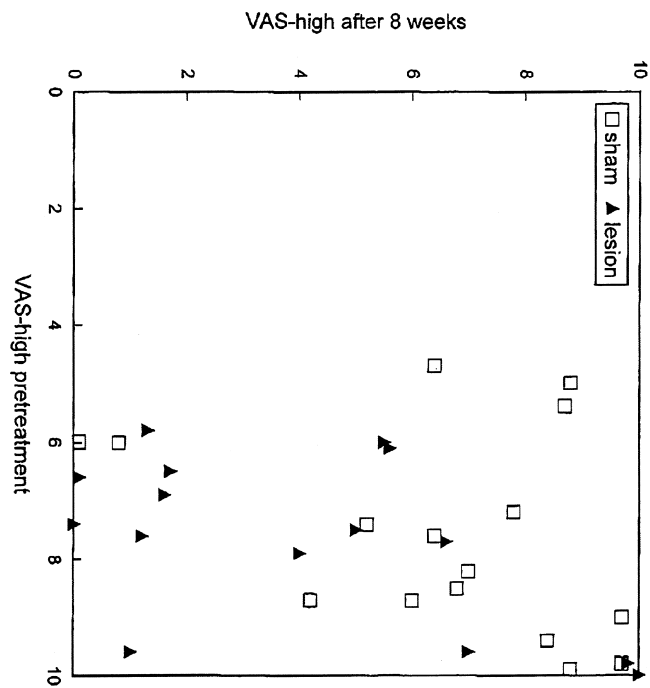


Figure 2. Scatter plot of visual analog scale high pain scores for each patient, before treatment and after 8 weeks (□ sham group; ▲ lesion group).

Statistical Analysis. The primary outcome variable was the percentage of successes at 8 weeks. To compare the success rates between the lesion and sham groups, odds ratios (OR) and their 90% confidence interval (CI) were calculated with a logistic regression model. Because of the small number of patients, it was unlikely that by randomization all prognostic variables were evenly distributed throughout both treatment groups. For that reason, all analyses were performed both adjusted and not adjusted for gender, age, duration of pain before treatment, the average pretreatment pain intensity, and Likert scores after diagnostic nerve blocks. As secondary outcomes, the differences between the sham and lesion groups in changes in VAS pain intensity scores, Oswestry disability scale, use of analgesic tablets, and COOP/WONCA quality of life and the 90% CIs were determined. This was also performed unadjusted using Student's *t* test and adjusted using a linear regression model. Because there were six secondary outcome variables, a global null hypothesis stating that all differences of these variables between the lesion and sham groups were zero, was tested using the ordinary least-squares (OLS) method.³⁴ The difference in follow-up data was analyzed using the log rank test.

Table 1. Pretreatment Characteristics by Allocated Treatment

	Sham Group (n = 16)	Lesion Group (n = 15)
Sex	6M, 10F	5M, 10F
Age, mean (SD) (yr)	41.4 (7.5)	46.6 (7.4)
Months of pain, median (range)	48 (12–192)	26 (12–120)
Pretreatment, mean (SD)		
VAS mean	5.2 (1.6)	5.2 (1.7)
VAS high	7.6 (1.7)	7.7 (1.5)
VAS low	3.0 (1.7)	2.9 (1.8)
Impairment according to Waddell	2.8 (1.1)	1.8 (1.5)
No. of analgesic tablets per 4 days [median (range)]	0 (0–12)	0 (0–15)
Oswestry Disability Scale [mean (SD)]	38.0 (13.1)	31.0 (14.2)
Coopwonca quality of life [mean (SD)]	21.6 (3.6)	20.2 (3.8)

■ Results

Demographic and Clinical Characteristics

In the period between June 1994 and April 1996, 256 consecutive patients with chronic low back pain were screened, of whom 92 fulfilled the study selection criteria. All underwent a diagnostic nerve block of the dorsal ramus of the segmental nerves at L3, L4, and L5, as described. After diagnostic block, 40 of them had a positive reaction (*i.e.*, temporary pain relief of at least 50% as assessed by a four-point Likert scale). Thirty-two entered the protocol and were randomized. The remaining eight patients did not enter the study for various reasons: four did not want to take part in a research trial, two reported no pain at all after the diagnostic nerve block, one had a mean VAS score lower than 4, and one did not want any nerve block at all. One patient who had been randomized was excluded from the analyses, because he did not want to return to the hospital after the study procedure. Patients who did not have temporary pain relief after a diagnostic block were treated in another way to relieve their symptoms.

Study Sample

In Table 1 the pretreatment characteristics of the patients in the lesion (n = 15) and sham groups (n = 16) are shown. There are no significant group differences in these variables (although the lesion group seemed somewhat older, used less medication, and was less disabled according to the Oswestry disability scale). According to Waddell's physical impairment assessment,⁵³ all patients were impaired except one in the radiofrequency group.

During the radiofrequency procedures, there were no problems in needle positioning. In the two groups, stimulation criteria did not differ. Average 2-Hz motor stimulation thresholds of 0.51 V (range, 0.15–0.85 V), 0.62 V (range, 0.25–0.80 V), and 0.58 V (0.3–0.75 V) were found at L3, L4, and L5, respectively. During the procedure, the anesthesia was adequate, and the patient could not determine whether he or she had received the radiofrequency treatment or the sham treatment. There were no complications during or after the interventions.

Tables 2 and 3 show the effects in the two experimen-

tal groups at 8 weeks. The mean VAS \pm SD after 8 weeks for the sham and lesion groups was 4.8 ± 2.5 and 2.8 ± 2.4 , respectively. The individual scores for VAS-high and VAS-mean pain scores are shown in Figures 2 and 3, respectively. The decrease in VAS-high pain scores was larger than the decrease in VAS-mean pain scores between the two compared groups, although both were statistically significant. The rate of successes was higher in the lesion group, and this result was significant, depending on the model used. The difference between the adjusted and the unadjusted odds ratio of success, was mainly caused by including the results of the Likert scale after diagnostic blocks in the model. Without this variable in the model, the adjusted odds ratio was also significant (4.77; 95% CI, 1.04–21.8). The logistic regression model demonstrated that patients who reported themselves free of pain after a diagnostic nerve block, showed a higher rate of success. The differences in effect on the VAS scores, global perceived effect, and the Oswestry Disability Scale in the lesion group were statistically significant, independent of the model.

Furthermore, for all secondary outcomes, the lesion group showed better results compared with the sham group. The OLS statistic based on all secondary outcome variables was $P = 0.003$. Eight weeks after treatment in the lesion and the sham groups two patients changed from impaired to unimpaired. These changes were not significant.

After 3, 6, and 12 months the number of successes in the lesion and sham groups was 9 and 4, 7 and 3, and 7 and 2, respectively. The log rank test showed a statistically significant difference ($P = 0.02$).

■ Discussion

This study, although in a relatively small sample, produced results that demonstrate that a radiofrequency denervation of the lumbar facet joints can be effective for pain reduction in a selected group of patients with lumbar zygapophysial joint pain. This finding is in accordance with the results published by Gallagher et al.²² To our knowledge, this study is the first to show that the reduction in pain correlates with a decrease in the intake of analgesics and improvement in disability status. Physical impairment variables⁵³ did not show a significant change during the trial, in accordance with Waddell and Main.⁵² These results documented a clinically significant effect of radiofrequency lumbar facet joint denervation

Table 2. Percentage of Successes of the Sham and Lesion Group After 8 Weeks of Treatment, the Unadjusted and Adjusted Odds Ratio (OR), and Their 90% Confidence Intervals

	Sham Group	Lesion Group	OR Unadjusted (90% CI)	OR Adjusted (90% CI)
Percentage of Successes	37.5	66.7	3.33 (0.97 to 11.5)	9.53† (1.50 to 60.5)

Table 3. Effects in Sham and Lesion Group After 8 Weeks of Treatment, the Unadjusted and Adjusted Differences Between Sham and Lesion Group, and Their 90% Confidence Intervals

	Mean Sham Group	Mean Lesion Group	Difference Unadjusted (90% CI)	Difference Adjusted (90% CI)
Change in VAS–mean	−0.43	−2.37	1.94* (0.24 to 3.64)	2.46* (0.72 to 4.20)
Change in VAS–high	−1.02	−3.64	2.62† (0.92 to 4.32)	3.39† (1.55 to 5.22)
Change in VAS–low	0.48	−1.85	2.33† (0.87 to 3.79)	2.42† (0.91 to 3.92)
Global perceived effect	0.37	1.33	−0.96* (−1.70 to −0.22)	−1.10* (−1.89 to −0.30)
Change in impairment according to Waddell	−0.07	−0.33	0.27 (−0.69 to 1.22)	0.31 (−0.74 to 1.35)
Change in no. of analgesic tablets per 4 days	1.75	−2.13	3.88* (1.19 to 6.57)	3.24 (−0.13 to 6.60)
Change in Oswestry Disability scale	1.69	−11.07	15.75† (4.16 to 21.35)	10.90* (1.76 to 20.0)
Change in Coopwonca quality of life	−1.62	−3.13	1.51 (−1.85 to 4.97)	2.27 (−1.77 to 6.30)

* One-tailed $P < 0.05$.† One-tailed $P < 0.01$.

on a long-term basis, a conclusion supported by the observation that the lesion group showed a significant reduction of pain on the VAS-high, VAS-mean, and global perceived effect, compared with the sham group. Especially the reduction of the VAS-high pain scores (4.1 points) in the lesion group indicates that the so-called peak of zygapophysial joint pain can be clinically reduced by this procedure.

Because of the small number of patients in the study, an uneven distribution of patient variables may still explain these results. However, the results of the adjusted and unadjusted analyses show that that this was not the case. As published previously, this effect tends to decrease gradually with passing time.^{15,25,32,50} Whether this phenomenon is explained by nerve regeneration remains to be determined.³³ The extent of the reported clinical effects of radiofrequency lumbar joint denervation is highly variable.^{10,13,15,18,19,22,24,27–30,35,36,38,40,45,47,48} Comparison of the current results with those in these

studies is not possible, because patients' baseline characteristics have not been reported.

This observation highlights the actual problem in defining the clinical relevancy of the lumbar “facet syndrome.” The current study and one other recent article on cervical facet joint denervation²⁵ demonstrate the existence of pain syndromes that can be treated effectively by facet joint denervation, thus operationally defining a facet syndrome. The clinical problem is how to reach the diagnosis of a facet syndrome. Clinical history and physical–diagnostic examination do not provide definitive clues about this diagnosis.⁴⁰ Radiologic findings are often aspecific and correlate poorly with symptoms.^{6,9,20} Bogduk and Long^{25,42} advocate the use of double-blind, placebo-controlled blocks to reach a precise diagnosis of facet pain. These investigators define diagnostic nerve blocks as positive when the patient reports himself or herself to be free of pain. This is in line with the current observation that patients who reported total pain relief (pain free) showed greater pain reduction after a radiofrequency lumbar facet denervation, compared with patients who reported only good pain relief. It implies that the clinical effect of this study would have been more pronounced when patients were included only after stating that they were pain free after a diagnostic block.

Finally, to our knowledge this is the first randomized trial in which results demonstrate the clinical efficacy of radiofrequency lumbar zygapophysial joint denervation in alleviating pain and functional disability in a selected group of low back pain patients.

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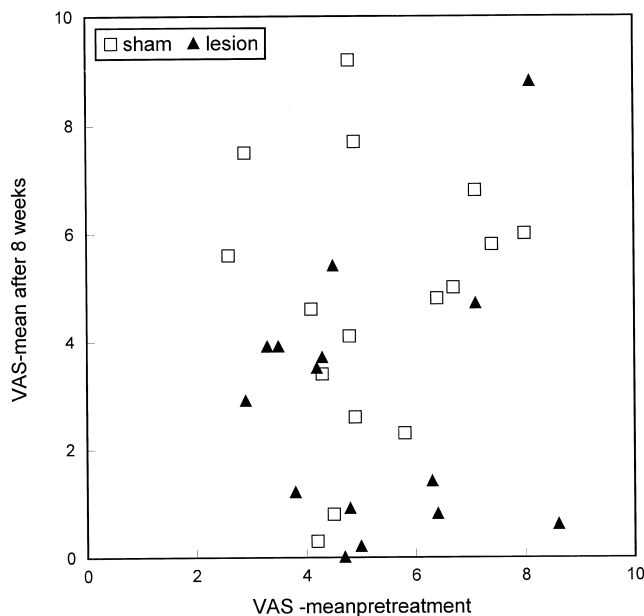


Figure 3. Scatterplot of visual analog scale mean pain scores for each patient, before treatment and after 8 weeks (□ sham group; ▲ lesion group).

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