Radiofrequency Denervation of Lumbar Facet Joints in the Treatment of Chronic Low Back Pain

A Randomized, Double-Blind, Sham Lesion-Controlled Trial

Roelof M. A. W. van Wijk, MD, PhD,† Jos W. M. Geurts, MD, PhD,*‡ Herman J. Wynne, PhD,§ Edwin Hammink, MD,* Erik Buskens, MD, PhD,‖ Richel Lousberg, PhD,¶ Johannes T. A. Knape, MD, PhD,* and Gerbrand J. Groen, MD, PhD**

Objectives: Radiofrequency facet joint denervation procedures have been common practice for 2 decades in treatment of chronic low back pain. We designed this multicenter, randomized, double-blind, sham treatment controlled trial to determine the efficacy of radiofrequency facet joint denervation, as it is routinely performed.

Methods: Inclusion criteria were low back pain, duration more than 6 months, and ≥50% Visual Analog Scale (VAS) reduction on diagnostic block. Exclusion criteria were prior radiofrequency treatment, radicular syndrome, coagulopathies, specific allergies, cancer, and pregnancy. A total of 81 out of 462 patients were randomized to undergo radiofrequency facet joint denervation or sham treatment. The first evaluation was carried out 3 months after treatment. Primary outcome was determined with a combined outcome measure comprising VAS, physical activities, and analgesic intake, from a twice-weekly recorded diary. Secondary outcome measures were the separate diary parameters, global perceived effect (complete relief, >50% relief, no effect, pain increase), and SF-36 Quality of Life Questionnaire.

Results: There were no dropouts before the first evaluation. The combined outcome measure showed no differences between radiofrequency facet joint denervation (n = 40; success 27.5%) and sham (n = 41; success 29.3%) ($P = 0.86$). The VAS in both groups improved ($P < 0.001$). Global perceived effect improved after radiofrequency facet joint denervation ($P < 0.05$). The other secondary outcome parameters showed no significant differences. Relevant costs were evaluated.

Discussion: The combined outcome measure and VAS showed no difference between radiofrequency and sham, though in both groups, significant VAS improvement occurred. The global perceived effect was in favor of radiofrequency. In selected patients, radiofrequency facet joint denervation appears to be more effective than sham treatment.

Key Words: low back pain, radiofrequency, facet joints

(*Clin J Pain* 2005;21:335–344)

Acute low back pain is one of the most common causes of pain in man.[1] Chronic low back pain (CLBP) develops in about 10% to 15% of patients,[2] though many more patients may experience recurrent episodes of back pain.[3] Chronic low back pain presents a major medical, social, and economic burden for Western societies.[4–6] Psychosocial factors have been shown to affect the occurrence and prognosis of CLBP.[7,8]

Lumbar zygapophyseal (facet) joints have been implicated as one of the causes of CLBP.[9,10] Percutaneous radiofrequency denervation of facet joints (RF-facet), as a symptomatic treatment of chronic pain attributed to these joints, has become common practice over the last decades in many Western countries. In the Netherlands (population about 15 million), RF-facet is performed more than 6000 times per year.[11]Although many retrospective studies have been reported, only 3 randomized controlled trials (RCTs) have been performed to evaluate the effect of this procedure in the treatment of CLBP.[12–14] The most recent trial did not show any efficacy of this treatment.[14] The other 2 RCTs, both with a limited number of patients, were able to demonstrate efficacy of RF-facet.[12,13] In a recent systematic review, Geurts et al concluded on the basis of these trials that there was moderate evidence that RF-facet is more effective for CLBP than placebo.[15] The present study is the largest RCT so far to assess the efficacy of RF-facet. We designed this study specifically to reflect common practice as much as possible. Therefore, although we performed no interventions between trial treatment and 3 months follow-up, further RF or injection procedures

Received for publication February 9, 2003; revised January 1, 2004; accepted January 11, 2004.

From the *Division of Perioperative Medicine, Anesthesiology and Pain Management, University Medical Center Utrecht, Utrecht; †Department of Anesthesiology, Onze Lieve Vrouwe Gasthuis, Amsterdam; ‡Department of Anesthesiology, Rijnstate Hospital, Arnhem; §Center for Biostatistics, Utrecht University, Utrecht; ‖Julius Center for Patient Oriented Research, Utrecht University, Utrecht; and ¶Roessingh Research and Development, Roessingh Rehabilitation Center, Enschede, The Netherlands.

Supported by a grant (OG 95-027) from the Dutch Health Insurance Council and by a contribution from the Pain Expertise Center Nijmegen.

Reprints: Roelof M.A.W. van Wijk, MD, PhD, Onze Lieve Vrouwe Gasthuis, PO Box 95500, Amsterdam 1090 HM, The Netherlands (e-mail: r.m.a.w.vanwijk@olvg.nl).

were allowed after this period if the initial treatment failed to ameliorate the pain sufficiently. In this way, we were able to evaluate the actual procedure of RF-facet as it is practiced in most pain clinics with RF facilities in the Netherlands and other countries, including a cost evaluation. The evaluated RF- facet procedure was consistent with the Dutch guidelines for anesthesiological pain management.[16]

MATERIALS AND METHODS

Patients

This multicenter, randomized, double-blind, sham lesion-controlled trial was coordinated at the Pain Clinic of the University Medical Center Utrecht, The Netherlands. It was conducted at the pain clinics of 4 medical centers in the Netherlands (University Medical Center, Utrecht; Rijnstate Hospital, Arnhem; Juliana Hospital, Apeldoorn; and Twenteborgh Hospital, Almelo) and approved of by all medical ethical committees. Written informed consent was obtained from all patients. All procedures were carried out on an outpatient basis by experienced anesthesiologists. Patients were assured that in case they experienced no pain relief after treatment, and this treatment being a sham lesion, an RF treatment would be offered.

After a standardized intake, including physical examination, patients more than 17 years of age were eligible if they had the following diagnostic features: continuous low back pain with or without radiating pain into the upper leg for more than 6 months with focal tenderness over the facet joints. Furthermore, no radicular syndrome should be present (ie, no sensory or motor deficits and no positive straight leg raising test). Finally, there should be no indication for low back surgery. Exclusion criteria were prior RF treatment, coagulation disturbances, allergies for radiopaque contrast or local anesthetics, malignancy, mental handicap or psychiatric condition precluding adequate communication, language problems, and pregnancy. If patients satisfied these conditions, diagnostic blocks were performed of the lumbar facet joints involved (see *Technique*). If patients had at least 50% pain reduction on a standard visual analog scale (VAS) applied after 30 minutes, they were included in the trial.

Between May 1996 and January 1999, 462 patients with CLBP were examined. A total of 81 patients (17.5%) could be selected and randomized for inclusion (Fig. 1).

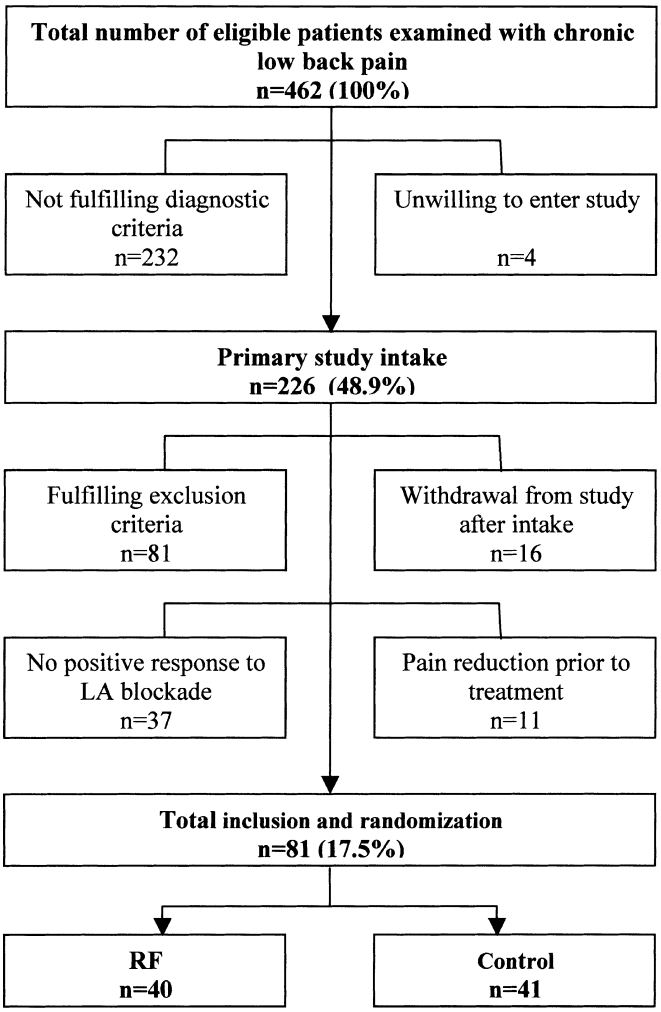

FIGURE 1. Flow chart of inclusions and randomization.

Technique

Diagnostic Block

Using 22G needles, a 2-level diagnostic intra-articular facet joint block with 0.25 to 0.5 mL radiopaque contrast and subsequently 0.25 to 0.5 mL lidocaine 2% per level was performed under fluoroscopic guidance in the area with most paravertebral tenderness on palpation. The joints between Th12–L2, L2–L4, or L4–S1 were blocked. A 2-level intra-articular block was chosen to reduce patient discomfort and to improve chances for a positive diagnostic block. In patients with bilateral low back pain, both sides were blocked in the same session.

Radiofrequency or Sham Lesion Procedure

Patients were randomized to RF or sham lesion (control) treatment. A C-arm image intensifier for fluoroscopic guidance (BV-25, Philips, Eindhoven, The Netherlands) was used. Neurostimulation and RF treatment were performed with a RF generator using a thermocouple with 10-cm electrodes (RFG-3C; 22G SMK-C10 electrode, 5-mm active tip. Radionics, Burlington, MA).[16–18] All patients were placed in a prone position on a radiolucent operating table. Under aseptic conditions, 3 or 6 (in case of bilateral pain) electrodes were placed at the site of the dorsal ramus medial branches of the relevant facet joints. The electrode tips were positioned parallel to the nerves at the angle between the superior articular process and the transverse process (Fig. 2), not further than the ventral border of the facet column (lateral view; Fig. 3). In all procedures, sensory and motor stimulation was applied at 50

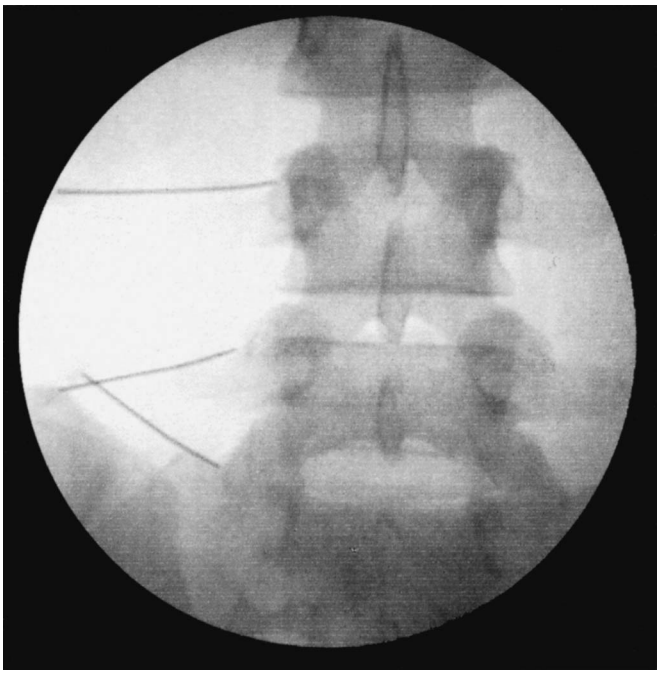

FIGURE 2. Radiofrequency electrodes in position at the angle between the superior articular process and the transverse process of the 4th and 5th lumbar vertebra and the sacral bone at the left side.

and 2 Hz. Sensory and motor stimulation threshold were required to be less than 0.5 V, respectively, at least 2 V. Subsequently, 0.5 mL of mepivacaine 2% was injected through each electrode to obtain a profound local anesthesia. Patients were treated with an RF lesion (80°C, 60 seconds; RF group) at the levels concerned. In the control group, electrodes and thermocouple probes were positioned similarly, but without switching on the RF current (see also *Randomization and Blinding*).

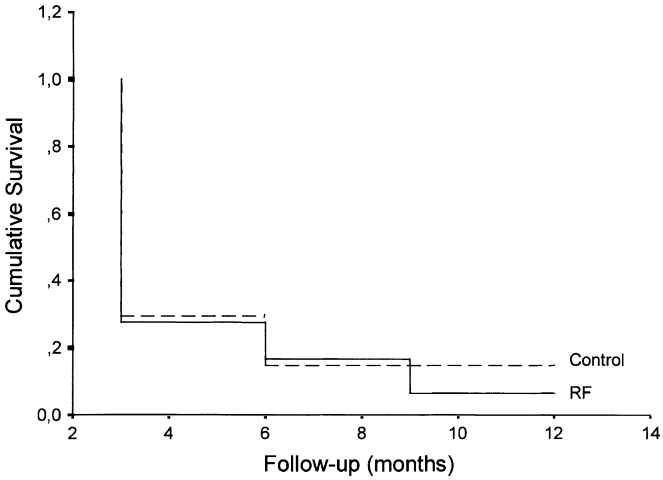

FIGURE 3. Lateral fluoroscopy image. Note position of the radiofrequency electrode tips in relation to the projection of the facet column.

Evaluation

Before treatment and at 3 months after treatment, median values of maximum pain intensity, daily activities, and analgesic intake were determined. Median values were calculated of 4 successive pain scores based on diaries that were completed twice a week by the patients 2 weeks before and at least 3 months following the treatment. To reduce bias, envelopes were supplied to insure weekly return of the diaries. The pain diary consisted of 2 VAS scales (both recording maximum pain level during the past 24 hours) specified for low back pain (VAS-back) and for pain radiating into the leg (VAS-leg), a physical activities scale (0–30 points; Table 1), and a report of analgesics used during the past 24 hours (analgesic intake scale, 0–8 points; Table 2). Furthermore, global perceived effect (GPE) was scored on a modified 4-point Likert scale (complete relief of pain, more than 50% relief, no effect, increase of pain) at 3 months follow-up. Quality of life was measured before and 3 months after treatment with the SF-36 questionnaire.[19] Depressive symptoms were assessed by the Zung Self Rating Depression Scale (Dutch version; Zung-DV).[20] Pain-related psychosocial and behavioral aspects were recorded with the Multidimensional Pain Inventory (Dutch Language Version; MPI-DLV).[21] The MPI(-DLV) assigns individual patients to 1 of 4 clusters.[22] It allows discernment between psychologically more or less "stable" and "unstable" patients (ie, Adaptive Coper and Average vs. Interpersonally Distressed and Dysfunctional).[23] Any temporary pain increase and subjective sensory or motor deficits due to the treatment were registered.

Primary outcome of treatment was determined using a predefined multidimensional combined outcome measure (COM) comprising a balance between changes in VAS-back and changes in daily physical activities and use of analgesics. Its construction reflected the desire of the investigators to use a primary outcome measure of binary character, which reflects and combines the presumably correlated changes in pain, daily behavior, and analgesic use in 1 measure. Moreover, it produces a reduced within-patient variability by combining 12 (self)-observations by the patient. Success of treatment was defined as: 1) a reduction of median VAS-back of at least 50%, without a drop in daily activities and/or rise in analgesic intake; or 2) a reduction of at least 25% of median VAS-back, with a simultaneous rise in daily activities of at least 25% and a drop in analgesic intake of at least 25%. Every outcome in which these criteria were not met was defined as failure.

An independent investigator made these calculations just prior to the 3-month control. In case of failure, the blinding was removed by the randomization center. The result was communicated to the treating clinician at the time of visit of the patient. If, after failure, treatment happened to be sham, RF treatment was offered. In case of success, blinding was continued, and follow-up was repeated at 6, 9, and 12 months.

Treatment-related costs within the first 3 months were determined for diagnostic blocks and RF (or sham) treatment. These comprised costs related to manpower, materials, depreciation and interest, overhead, and accommodation and cleaning. All cost estimates were based upon actual costs rather than charges. These were determined by using the time involved

TABLE 1. Physical Activities Scale*

Physical Activities	
On every specific activity the patient should answer if it can be performed "without difficulty," "with difficulty," "with help from others," or if it is "not possible," scoring responses 3, 2, 1, or 0 points. Maximum is 30 points	
Sitting down and standing up from a chair	Taking a long walk
Getting in and out of bed	Washing oneself (bathing, showering)
Dressing, putting on shoes, undressing	Bending over, lifting something
Sitting down during a longer period	Work, housekeeping, more strenuous hobbies
Walking outside	Fixing minor things at home

*Derived from the Dutch Central Bureau of Statistics.

with each procedure multiplied with hourly incomes of staff and hourly costs of accommodation and day care facilities, costs of purchase of materials, and relevant administration, depreciation and interest, and overhead costs. Costs of additional medical consumption, defined as medical, paramedical, and pharmaceutical treatment during this period, were determined by a questionnaire.

Statistics

Based on previous experience, treatment success rates of between 60% and 70% were expected at 3 months follow-up as evaluated by the primary outcome criterion (COM). Against an estimated sham (placebo) success rate of 29%, as found in this study, this leads to powers of between 79% and 97% for the sample sizes of 2 × 40 patients chosen for this study.

The results of the COM at 3 months follow-up were tested using the χ^2 test. Kaplan-Meier survival curves of COM outcomes were constructed for the RF and control group, and the statistical significance of difference between the curves was calculated with the log rank test. Association between the components constituting the COM (VAS-back, physical activities, and analgesic intake) was assessed by computing pairwise partial correlation coefficients for consecutive scores during 8 weeks (prior to the 3-month follow-up) within patients between 2 of these variables, controlling for the third variable. Secondary outcome parameters like VAS-back, VAS-leg, physical activities, analgesics intake, GPE, and SF-36 were tested with χ^2 and *t* tests. Potential effects of demographic and clinical covariables as well as the results of the Zung-DV, DPQ, and MPI-DLV scales were assessed as to their effect on the main outcome parameters in both groups using multiple logistic or linear regression. All reported *P* values are two-sided.

TABLE 2. Analgesics Intake Scale: Maximum Score is 8 Points*

Points	Analgesics and Classification†		Points	Analgesics and Classification†	
0	No analgesics				
	Group I analgesics			Group II analgesics (continued)	
1 (level 1)	Paracetamol	≤2 g per day	4	Group I-1 + codeine	>60 mg per day
	Naproxen	≤750 mg per day		Group I-1 + buprenorphine	>0.6 mg per day
	Diclofenac	≤100 mg per day		Group I-1 + tramadol	>200 mg per day
	Ibuprofen	≤800 mg per day			
	Mebutan	≤1000 mg per day	5	Group I-2 + codeine	≤60 mg per day
				Group I-2 + buprenorphine	≤0.6 mg per day
2 (level 2)	Paracetamol	>2 g per day		Group I-2 + tramadol	≤200 mg per day
	Naproxen	>750 mg per day			
	Diclofenac	>100 mg per day	6	Group I-2 + codeine	>60 mg per day
	Ibuprofen	>800 mg per day		Group I-2 + buprenorphine	>0.6 mg per day
	Mebutan	>1000 mg per day		Group I-2 + tramadol	>200 mg per day
3	Group II analgesics		7	Group III analgesics	
	Group I-1 + codeine	≤60 mg per day		Opioids (except codeine)	
	Group I-1 + buprenorphine	≤0.6 mg per day			
	Group I-1 + tramadol	≤200 mg per day	+1	Comedication, if used (benzodiazepines, antidepressants, anticonvulsants)	

*Geurts JWM, van Wijk RMAW. Minimally invasive procedures in the treatment of chronic low back pain [PhD thesis]. Utrecht University, 2001:79.
†Group classification according to World Health Organization analgesic ladder.

TABLE 3. Patient Characteristics and Baseline Values of Outcome Parameters

Patient Characteristics					
	RF	**Control**		**RF**	**Control**
No. patients	40	41	Duration of pain (%)		
Mean age, yrs (SD)	46.9 (11.5)	48.1 (12.6)	≤2 yrs	8 (22.5)	9 (22.0)
Male/female	10/30	13/28	2–5 yrs	10 (25.0)	12 (29.3)
Marital status (%)			>5 yrs	21 (52.5)	19 (48.8)
Single	7 (17.5)	9 (22.0)	Regional distribution of pain (%)		
Married/living together	33 (82.5)	32 (78.0)	Th12–L2	1 (2.5)	2 (4.9)
Educational level* (%)			L2–L4	4 (10.0)	3 (7.3)
Low	16 (40.0)	17 (41.4)	L4–S1	35 (87.5)	36 (87.8)
Middle	12 (30.0)	8 (19.5)	Site of pain (%)		
High	12 (30.0)	13 (31.7)	Unilateral	25 (62.5)	24 (58.5)
			Bilateral	15 (37.5)	17 (41.5)
Employment status (%)			Zung† (%)		
Employed	17 (42.5)	21 (51.2)	<50	30 (76.9)	30 (75.0)
Unemployed	23 (57.5)	20 (48.8)	≥50	9 (23.1)	10 (25.0)
Low back surgery (%)			MPI-DLV‡ (%)		
None	25 (62.5)	25 (60.9)	DYS + ID	22 (55.0)	20 (48.8)
≥1 operations	15 (37.5)	16 (39.1)	AC + AV	18 (45.0)	17 (41.5)

Baseline Values of Outcome Parameters					
	RF	**Control**		**RF**	**Control**
VAS-back§ (SD)	5.8 (1.8)	6.5 (1.8)	SF-36 (SD)		
VAS-leg§ (SD)	4.2 (2.6)	4.1 (2.8)	Physical functioning	42.9 (19.3)	33.8 (17.0)
Physical activities§ (SD)	20.6 (4.2)	18.4 (4.5)	Social functioning	59.7 (23.1)	53.0 (24.7)
Analgesics intake§ (SD)	1.0 (1.0)	1.5 (1.7)	Physical role restriction	20.0 (37.6)	18.4 (21.8)
			Emotional role restriction	55.8 (45.5)	70.3 (41.4)
			Mental health	62.9 (21.8)	70.2 (16.8)
			Vitality	43.5 (21.6)	49.2 (19.6)
			Pain	37.3 (15.6)	31.2 (15.3)
			General health	56.8 (21.9)	57.3 (19.8)
			Health changes‖	36.3 (22.6)	28.4 (20.5)

*Low, elementary school/lower professional education; Middle, high school/middle professional education; High, college/university.

†Zung Self Rating Depression Scale: <50: normal; ≥50: minimal to moderate depression. No serious depression was found. Values of 1 patient in each group missing.

‡Multidimensional Pain Inventory-Dutch Language Version. Patients are reported to belong to 1 of 4 clusters: dysfunctional (DYS), interpersonally distressed (ID), adaptive coper (AC), or average (AV). Patients in the last 2 clusters are considered to be more or less psychologically "stable." In the control group, 3 patients were assessed as anomalous; values of 1 patient are missing.

§Median value of 4 measurements during 2 weeks.

‖Compared to 1 year before.

Randomization and Blinding

Randomization was performed independently and in a separate setting by the Center for Biostatistics (Utrecht University). Patients were stratified according to sex (M/F) and history of low back surgery (+/−), as previous studies suggested that these factors might be related to outcome. Four sets of closed envelopes (M+, M−, F+, F−) were thus produced. Just before treatment, an envelope was drawn at random from the appropriate set of envelopes and opened by an independent physician, who read the contents and accordingly instructed the RF generator setup by a technician. These contents, including additional information on patient identity, were then placed into another envelope, which was sealed and returned to the randomization center. Both RF and sham procedures were carried out identically except for the RF-induced temperature rise in the RF group. The RF generator display was turned away from the operating table, and no visual or auditory signals could inform the patient or treating physician on the nature of the procedure. As a profound local anesthesia was applied in both the RF and sham procedure, patients were not able to tell which treatment they were receiving. If at 3 months follow-up the COM showed failure of treatment, blinding was ended. On medical indication, blinding could be ended at an earlier moment.

RESULTS

Forty patients were randomized to RF and 41 patients to sham treatment (Fig. 1). After randomization and before the 3-month follow-up, no dropouts occurred. In none of the cases was blinding ended prematurely. Patient characteristics and baseline values showed adequate matching between both

TABLE 4. Outcome After 3 Months

	RF	Control
No. of patients	40	41
Success defined by COM [n (%)]	11 (27.5)	12 (29.3)
Mean change in VAS-back*	−2.1	−1.6
Mean change in VAS leg*	−1.1	−0.7
VAS-back reduction ≥2 points* [n (%)]	19 (47.5)	20 (48.8)
VAS-back reduction ≥25%* [n (%)]	25 (62.5)	20 (48.8)
VAS-back reduction ≥50%* [n (%)]	13 (32.5)	14 (34.1)
Mean change in physical activities*	1.5	0.9
Mean change in analgesics intake*	−0.1	−0.2
Global perceived effect on back-pain (n RF = 39) [n (%)]		
≥50% pain relief	24 (61.5)†	16 (39.0)
<50% pain relief or pain increase	15 (38.5)	25 (61)
Global perceived effect on leg pain (n RF = 38) [n (%)]		
≥50% pain relief	19 (50)	15 (36.6)
<50% pain relief or pain increase	19 (50)	26 (63.4)
SF-36 (mean difference 3–0 mos) (SD)		
Physical functioning	4.7 (16.9)	7.8 (19.7)
Social functioning	5.3 (36.1)	2.6 (29.6)
Physical role restriction‡	10/3	11/8
Emotional role restriction‡	1/0	2/3
Mental health	2.7 (26.8)	0.7 (23.9)
Vitality	5.3 (14.6)§	−2.4 (17.7)
Pain	11.8 (22.9)	11.6 (20.6)
General health	1.8 (13.6)	−1.3 (17.5)
Health change compared to 1 yr before‡	22/4	18/2

*Median value of 4 measurements during 2 weeks.
†χ^2 test, $P = 0.044$.
‡The number of patients is shown that went up/down 1 or more classes.
§ANOVA, $P = 0.03$.

groups (Table 3). The results of all outcome parameters at 3 months follow-up are summarized in Table 4. The outcome of the COM showed no differences between RF (success 27.5%) and sham (success 29.3%) (χ^2 test, $P = 0.86$). Kaplan-Meier survival curves showed no significant differences (log rank test, $P = 0.60$) during the 1-year follow-up (Fig. 4). Also, no differences in effect between RF and control could be found when measured by VAS-back, VAS-leg, physical activities, or analgesics intake. Nonetheless, in both groups VAS-back was significantly reduced (RF: δVAS = 2.1, $P = 0.0001$; control: δVAS = 1.6, $P = 0.0003$), and in the RF group VAS-leg (δVAS = 1.1, $P = 0.0059$). These effects persisted throughout the 1-year follow-up (Figs. 5 and 6). These long-term results have to be interpreted with care, because blinding was ended at 3 months follow-up in more than 70% of patients, and some patients in both groups were lost to follow-up. The GPE showed a significant difference in favor of RF treatment (≥50% pain relief: 61.5% vs. 39%, $P = 0.044$). The SF-36 questionnaire showed an improvement of "vitality" in the RF group. No significant differences were observed in the occurrence of treatment-related pain and subjective sensory or motor changes (Table 5).

Odds ratios of the 3-month primary effects (COM, VAS-back reduction, and GPE) without and with correction for selected covariables, among them the original stratification variables, sex, and low back surgery history, are presented in Table 6. The χ^2 test results for interactions and for within-stratum effects have been given if $P < 0.05$. After correction for multiple testing, there are no statistically significant covariate effects or interactions. Nevertheless, there is an indication for GPE showing RF to be superior to sham in female patients ($P = 0.018$), older patients ($P = 0.022$), patients with longer pain history ($P = 0.019$), patients with employment ($P = 0.008$), and patients without low back surgery ($P = 0.032$). A MPI-DLV cluster × randomization (treatment group) interaction effect is suggested if measured by the COM ($P = 0.03$), reduction of VAS-back ($P = 0.075$), and GPE ($P = 0.08$), implying that patients classified as Adaptive Copers or Average possibly perform better than those classified as Interpersonally Distressed or Dysfunctional. However, differential treatment responses based on MPI-DLV clustering were not part of the primary study design, and these effects are among many others tested statistically.

Association between the components constituting the COM (VAS-back, physical activities, and analgesics intake) was assessed by computing partial correlation coefficients (within patients) between 2 of these variables, controlling for the third variable. As expected, VAS-back and physical

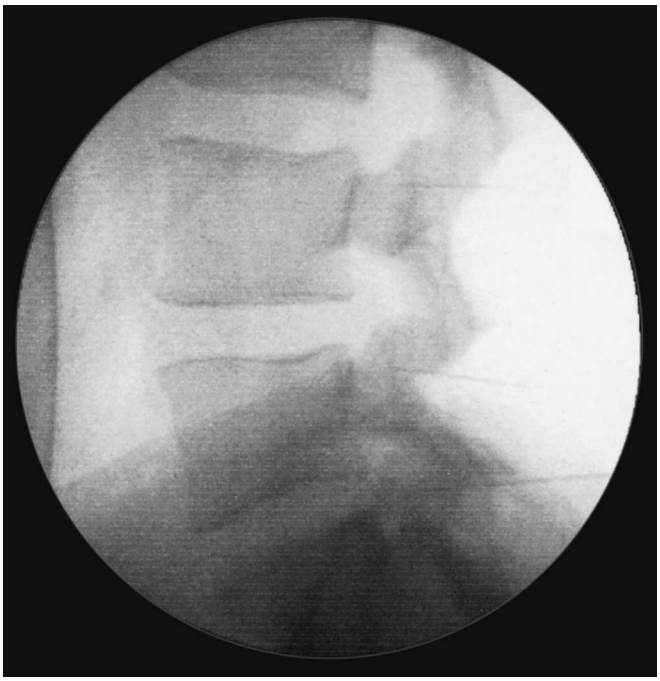

FIGURE 4. Kaplan-Meier curves of radiofrequency and sham lesion (control) group [*P*(log rank) = 0.60].

activities showed a negative partial correlation controlled for analgesic intake ($r = -0.50$; $P < 0.01$), and VAS-back and analgesics intake showed a positive correlation controlled for physical activities ($r = 0.17$; $P < 0.01$).

Long-term analysis was complicated by the low success rates when measured by COM and the subsequent ending of blinding in the majority of cases at 3 months follow-up. Subsequent diversity in timing and type of additional treatments, albeit allowed under our protocol, made further long-term analysis not feasible.

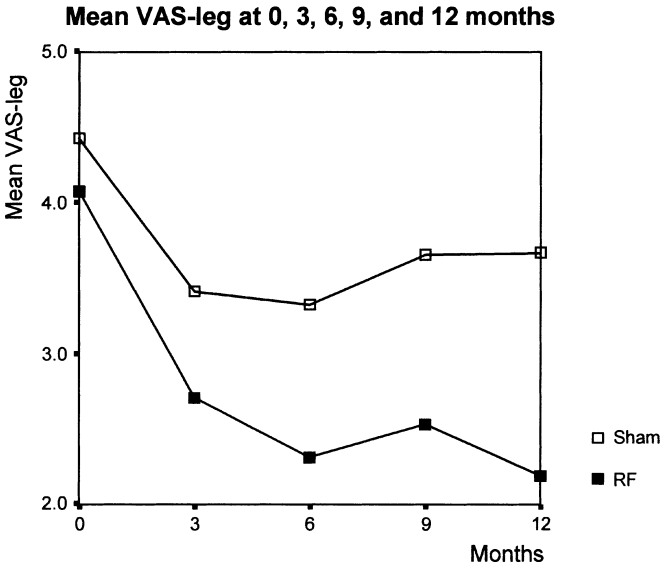

FIGURE 5. Effects on VAS-back during 1-year follow-up.

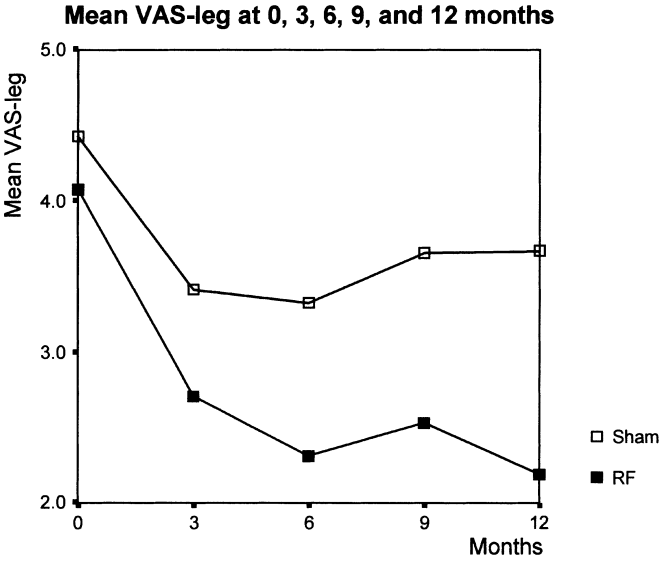

FIGURE 6. Effects on VAS-leg during 1-year follow-up.

The treatment related costs of either RF or sham treatment totaled €285 (€1 ≈ U.S. $1) in the first 3 months. The mean costs of additional medical consumption were €82 (RF group) and €98 (control group). This is mainly based on higher costs for medical and paramedical consultations in the control group combined with higher pharmaceutical costs in this group (which was in accordance with a baseline higher analgesics intake in the control group). The RF group scored higher in costs of alternative medicine consultations. Overall, these results would yield an average cost-effectiveness ratio of

TABLE 5. Adverse Events and Complications After RF or Sham Treatment

	RF	Sham
Treatment-related pain* [n (%)]		
None	12 (30.8)	21 (53.8)
Little	4 (10.3)	4 (10.3)
Moderate	9 (23.0)	4 (10.3)
Severe, necessitating analgesics	14 (35.9)	10 (25.6)
Total no. patients analyzed†	39	39
Change of sensibility* [n (%)]		
Unaltered	37 (94.8)	39 (97.5)
Discrete	—	1 (2.5)
Irritating	1 (2.6)	—
Evident dysaesthesia or allodynia	1 (2.6)	—
Total no. patients analyzed†	39	40
Loss of motor function* [n (%)]		
Unaltered	36 (94.7)	39 (95.2)
Discrete	2 (5.3)	1 (2.4)
Irritating	—	1 (2.4)
Evident motor loss	—	—
Total no. patients analyzed†	38	41

*No statistically significant differences were found.
†Due to incomplete data, not all patients could be analyzed.

TABLE 6. Primary and Most Important Secondary Outcome Parameters After 3 Months in Relation to Covariables

	Combined Outcome Measure					Median VAS-back		Global Perceived Effect (Back Pain)				
	RF		Control					RF		Control		
Covariables	Success/ Failure (n)	Success (%)	Success/ Failure (n)	Success (%)	OR (95% CI) P‡	F ∂VAS†	Control ∂VAS‡	Success/ Failure (n)	>50% Pain Relief (%)	Success/ Failure (n)	>50% pain relief (%)	OR (95% CI) P‡
Overall outcome	11/29	27.5	12/29	29.3	0.9 (0.3–2.4)	2.1	1.6	24/15	61.5	16/25	39.0	2.5 (1.0–6.1) 0.044
Sex					0.9 (0.3–2.4)							2.5 (1.0–6.1)
Male	2/8	20.0	6/7	46.2		1.2	1.8	5/4	55.0	7/6	53.8	
Female	9/21	30.0	6/22	21.4		1.9	1.3	19/11	63.3	9/19	32.1	0.018
Age					0.9 (0.3–2.4)							2.5 (1.0–6.1)
18–40 yrs	4/9	30.0	4/8	33.3		2.3	1.7	7/6	53.8	6/6	50.0	
>40 yrs	7/20	25.9	8/21	27.6		1.8	1.3	17/9	65.4	10/19	34.5	0.022
Duration of pain					0.9 (0.3–2.4)							2.5 (1.0–6.1)
<2 yrs	3/6	33.3	2/7	22.2		2.0	2.3	4/4	50.0	3/6	33.3	
2–5 yrs	3/7	30.0	5/7	41.6		2.1	2.3	6/4	50.0	7/5	58.3	
>5 yrs	5/16	23.8	5/15	25.0		2.1	2.0	14/7	66.6	6/14	30.0	0.019
Marital status					0.7 (0.3–2.0)							1.9 (0.8–4.8)
Single	1/4	20.0	1/4	20.0		2.6	0.8	3/2	60.0	2/3	40.0	
Married/living together	9/24	27.2	11/21	34.3		1.8	1.9	19/13	59.4	14/18	43.8	
Educational level					0.9 (0.3–2.5)							2.5 (1.0–6.1)
Low	4/12	25.0	5/12	29.4		2.2	1.4	12/4	75.0	7/10	41.2	0.049
Middle	4/8	33.3	3/5	37.5		1.8	1.9	4/7	36.4	3/5	37.5	
High	3/9	25.0	3/10	23.1		2.1	1.9	8/4	66.6	5/8	38.5	
Employment status					0.9 (0.3–2.4)							2.5 (1.0–6.1)
Unemployed	7/16	30.4	7/13	35.0		1.9	1.9	11/11	50.0	9/11	45.0	
Employed	4/13	23.5	5/16	23.8		1.8	1.6	13/4	76.5	7/14	33.3	0.008
Low back surgery					0.9 (0.3–2.4)							2.5 (1.0–6.1)
None	8/17	32.0	6/19	24.0		2.5	1.5	16/8	66.6	9/16	36.0	0.032
≥1 operations	3/12	20.0	6/10	37/5		1.7	1.8	8/7	53.3	7/9	43.8	
Zung-DV					0.9 (0.3–2.5)							2.7 (1.1–7.1)
<50	9/21	30.0	11/21	34.3		2.3	1.8	19/10	65.5	15/17	46.9	
≥50	2/8	20.0	1/8	11.1		1.4	1.0	5/5	50.0	1/8	11.1	
MPI-DLV§												2.2 (0.9–5.5)
DYS + ID	3/19	13.6	8/13	38.1	0.3 (0.1–1.2)	1.6	2.1	11/11	50.0	10/11	47.6	
AC + AV	8/10	44.4	4/13	23.5	2.6 (0.6–11.2)	2.6	1.1	13/4	76.5	6/11	35.3	
Interaction‖					0.030							

*Median value of 4 measurements during 2 weeks.
†VAS reduction after 3 months.
‡χ^2 test (only $P < 0.05$ given, no correction for multiple testing).
§Multidimensional Pain Inventory-Dutch Language Version. Patients are reported to belong to 1 of 4 clusters: dysfunctional (DYS), interpersonally distressed (ID), adaptive coper (AC), or average (AV). Patients in the last 2 clusters are considered to be more or less psychologically "stable". In the control group, 3 patients were assessed as anomalous; values of 1 patient are missing.
‖MPI-DLV cluster × randomization interaction effect (see text).
OR, odds ratio (Mantel Haenszel); CI, confidence interval.

€136 and €178 per point VAS reduction after 3 months for RF and sham treatment, respectively. If costs of additional medical consumption were to be added, this would result in €175 (RF) and €239 (control), respectively.

DISCUSSION

This trial, involving 81 patients, is the largest RCT so far on the efficacy of RF-facet in the treatment of CLBP, the other 3 trials ranging from 20 to 70 patients.[12–14] No differences in primary outcome (COM) were found after 3 months between RF and sham lesion-treated patients. The sample sizes in this study warrant sufficient power, so that relevant success rates on the basis of COM of 60% to 70% can be excluded with probabilities of between 79% and 97%. The placebo (sham) success rate can be estimated from this study to be 29%. The negative correlation between VAS and physical activities and the corresponding positive correlation between VAS and analgesic intake for consecutive scores in patients' diaries are

as expected, because a decrease in VAS would probably lead to an increase in daily activities and a reduction in analgesic use. In the design phase of this trial, we postulated that uniting these measurements in 1 COM for success or failure of treatment would contribute to the validity of this end point. We could be assured that any patient who tended to reduce pain by restriction in daily activities and/or an increase in analgesic use would be correctly singled out as "failure to treatment" by the COM. However, as physical activities and analgesic intake hardly improved in our trial population, these parameters have had a disproportionate impact on the COM outcome. Thus, our primary outcome measure should be interpreted with care. Still, even on the basis of VAS scores alone, the outcomes in both RF and control groups do not differ significantly. Nevertheless, both groups show a significant decrease in VAS, which lasted during the 12-month follow-up. Though no further analysis was deemed feasible because of the mix of additional treatments performed between 3 and 12 months, one may tentatively conclude that these additional treatments had a lesser impact on the overall VAS reduction than the first RF or sham treatment, although they could have maintained the initial VAS reduction. It is not clear why VAS-back (both RF and sham group) and VAS-leg (only RF group) were significantly reduced compared with baseline values. For the RF group, the RF effect could in part be held responsible. Diagnostic blocks could not have influenced the results, because baseline measurements were taken afterward. The application of a strong local anesthetic to the target nerves could in part be responsible. The phenomenon of prolonged analgesic effect after local anesthetic infiltration is known.[24] Our findings on significant VAS reduction are not in line with those by Leclaire et al.[14] It is quite possible that they had already obtained some therapeutic effect with the diagnostic blocks with the added steroids. Baseline values were obtained after these blocks, which could have influenced their eventual findings.

Of all secondary outcome parameters, only GPE demonstrated a significant difference in favor of the RF group. This measure seems to mirror "the patient's view" best. Quality of life did not improve in either group, except for the SF-36 "vitality" item in the RF group. A clear-cut explanation for this finding cannot be given. Although depressive state has been reported to affect therapeutic outcome,[25] this was not observed in the present study. Interestingly, we found that psychologically "stable" patients (as measured by MPI-DLV) appear to respond better to a unimodal somatic-oriented therapeutic intervention, such as RF. This is reflected in COM, VAS-back, and GPE outcomes. This post hoc finding is in line with a tailor-made subgroup-specific approach as advocated by Turk,[26] but remains to be verified in future controlled studies.

In contrast to the results of previously published controlled trials,[12,13] and a recent prospective uncontrolled study on RF-facet in 15 patients,[27] the present study demonstrates no significant difference in VAS reduction between the RF and control group. Our results correspond with those of a very recently published RCT in 70 patients.[14]

We emphasize that our trial was designed to reflect common clinical practice as much as possible. Thus, contrary to the other studies,[12–14,27] previous low back surgery or concomitant other causes for CLBP were not exclusion criteria. In our series, low back surgery history had no effect on outcome, except for a better effect of RF versus sham when measured with the secondary outcome measure GPE in nonoperated patients. Because different sources of pain may coexist in CLBP patients, eg, intervertebral discs, facet joints, sacroiliac joints, ligaments, and muscles,[10,28,29] this may have influenced our study population. As physical diagnostic criteria for lumbar facet joint syndrome appear to be unreliable and nonspecific,[30,31] diagnostic blocks are regarded essential when selecting patients for RF-facet. These can be performed intraarticularly or at the medial branch of the dorsal ramus,[32,33] both with comparable diagnostic value.[34] Uncontrolled diagnostic blocks may have false-positive effects with a low predictive value.[33,35] This effect probably increases if a steroid is added to the local anesthetic, as was done in 2 of the 3 previously performed RCTs.[12,14] With controlled diagnostic blocks, in which outcome is judged by the expected duration of effect of successive random injections of lidocaine and bupivacaine, these results can be improved considerably.[33,36] However, because our primary aim was to test common clinical practice,[16] controlled diagnostic blocks were not performed. Thus far, only 1 observational study on lumbar RF-facet applied a (modified) controlled diagnostic block protocol.[27] Yet, although stating that the prevalence of chronic lumbar facet joint pain ranges from 15% to 40%, only 15 out of 460 (3.3%) patients presenting with CLBP could be selected, compared with 17.5% in our present study. In contrast, it has been noted that controlled diagnostic blocks are time-consuming and superfluous because of the low risk/benefit ratio for RF-facet.[35]

Although our RF technique is the same as used by van Kleef et al and Sluijter and Mehta,[13,17] Leclaire et al, though using the same size electrodes (22G), performed 2 lesions at each level.[14] In other studies, thicker electrodes (18G and 16G) were used.[12,27,37] In the study by Dreyfuss et al, most probably a considerably greater lesion area is produced because the much larger electrode was retracted 4 to 5 mm before making a second lesion.[27]

No improvement in physical function was found, despite significant reduction in pain scores. This underlines the need to combine these procedures with subsequent structured rehabilitation programs.

Overall costs per point VAS reduction were 24% lower in the RF group compared with the control group. Conclusions cannot be drawn, however, because of the relatively low frequency of additional medical consumptions in the 3-month follow-up period.

In this trial, reflecting common clinical practice as much as possible, we found no statistically significant effect of RF-facet as compared with sham treatment in patients with CLBP when using a predefined, multidimensional COM. In VAS scores, no difference in effect was observed, although in both RF and control group, a comparable significant decrease in VAS was found. However, the GPE outcome was clearly in favor of the RF treatment. Also, outcomes suggest a better response to RF compared with sham treatment in psychologically "stable" patients, females, older patients, patients with

a longer pain history, patients with employment, and patients without previous low back surgery.

In conclusion, RF lumbar facet joint denervation appears to have a better effect compared with sham treatment in a selected group of patients. Future research should be directed toward improvement of RF technique and psychologic profile evaluation as part of a selection procedure for RF treatment.

ACKNOWLEDGMENTS

The authors thank the patients that participated in the study and the referring medical doctors. They also thank all contributors to the study: E. T. Kamphuis, MD, PhD, A. J. de Gier, MD, E. J. Buijs, MD, A. S. M. Wassink, MD, anesthesiologists; J. M. S. P. Quirijnen, PhD, and M. P. Mastenbroek, medical psychologists; D. G. Roseval, MD, F. D. M. Hommes, MD, A. J. van Nie, MD, E. J. Bijsmans, MD, residents in anesthesiology; C. G. M. M. Beckers, coordination; the qualified nurse-technicians assisting with the procedures; all secretaries from the pain clinics administrations; T. Buijs-van der Woude, cost analyses; K. G. M. Moons, PhD, clinical epidemiologist; P. Anema, information technologist; B. M. G. Annink, B. M. den Bandt, trial bureau; J. M. Kemmeren and M. Oldenborg, data analyses. Professors A. J. P. Schrijvers, MD, PhD, and C. J. Kalkman, MD, PhD, are acknowledged for their general advice and support.

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