ORIGINAL ARTICLE

Pulsed Radiofrequency in Lumbar Radicular Pain: Clinical Effects in Various Etiological Groups

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■ **Abstract**

Background: The purpose of this study was to evaluate the effectiveness of pulsed radiofrequency (PRF) applied to the lumbar dorsal root ganglion (DRG).

Methods: A retrospective analysis of 54 consecutive patients who underwent 75 PRF procedures was performed. The patients were divided into three groups according to the etiology of the lesion (herniated disc [HD], spinal stenosis [SS], and failed back surgery syndrome [FBSS]). The analgesic efficacy of the technique was assessed using a 10-point Numeric Rating Scale (NRS) at baseline and, along with the Global Perceived Effect (GPE), at 30, 60, 90, and 180 days. The reduction in medications and the number of complications associated with the technique were assessed.

Results: A decrease in the NRS score was observed in patients with HD ($P < 0.05$) and SS ($P < 0.001$), but not in those with FBSS. The GPE scores confirmed this finding. No complications were noted.

Conclusions: We observed that PRF of the DRG was significantly more efficacious in HD and SS than in FBSS patients. The application of PRF was not effective in FBSS. ■

Key Words: pulsed radiofrequency, dorsal root ganglion, failed back surgery, spinal stenosis, radiofrequency thermocoagulation

INTRODUCTION

Radiofrequency (RF) thermolesioning adjacent to the dorsal root ganglion (DRG) has been employed for pain relief in patients with cervicobrachial pain,[1–3] thoracic radiculopathy,[4] and chronic lumbar radicular pain (LRP).[5] Despite its widespread use and well-documented efficacy, this option does not appear to be an ideal modality of treatment for LRP because neurodestructive methods for the treatment of neuropathic pain are in principle generally considered inappropriate. Denervation dysesthesia and other neurological adverse effects have been described.[1–5]

Sluijter et al. described the use of isothermal RF treatment, known as pulsed radiofrequency (PRF), in 1998.

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PRF is not associated with significant destruction of nerve tissue.[6] This technique, in which the target structure is exposed to the RF electric field without raising the mean tip temperature to neurodestructive levels, is regarded as a neuromodulatory technique rather than an ablative one.[7,8] There are no reports in the literature of sensory or motor changes following PRF.[8,9] The use of PRF would therefore seem more appropriate than radiofrequency thermolesioning (RFTC) for the treatment of LRP.

In this retrospective study, we have analyzed the efficacy of PRF in the treatment of three different groups of patients with LRP: herniated disc (HD), spinal stenosis (SS), and failed back surgery syndrome (FBSS).

MATERIALS AND METHODS

We performed a retrospective analysis of patient records stored in the hospital database for all patients suffering from LRP over 18 years of age treated between January 2001 and December 2003. The study was approved by the local clinical ethics committee. In all the cases, the diagnosis of LRP was confirmed by positive selective radicular nerve block. This technique was explained to each patient and informed consent was obtained before undertaking any procedure.

Our sample consisted of 54 patients who underwent 75 PRF procedures. While most patients had this technique performed in one DRG, some patients required treatment to more than one DRG (usually at an adjacent level). When more than one DRG was treated at a single setting, this was considered a single procedure. Therefore, the 75 procedures performed refer to the number of individual treatments, independent of the number of levels treated on each occasion. In both SS and FBSS, we treated the affected levels as determined by diagnostic selective radicular nerve blocks. The patients were divided into three groups according on the etiology of their pain: HD ($n = 29$), SS ($n = 12$) or FBSS ($n = 13$). All diagnoses were based on a combination of clinical symptoms, magnetic resonance imaging and electromyography. In all patients, the predominant clinical finding was lumbosacral pain: radicular in distribution and burning and/or tingling in nature. Patients were excluded from study when the predominant symptom was intermittent claudication in the group of SS or low back pain in the FBSS group.

All patients undergoing PRF had a positive response (50% improvement in the symptoms lasting at least 6 hours) to selective radicular nerve block with local anesthetic (bupivacaine 0.125%) at the affected level.

Table 1. Global Perceived Effect: 7-Point Likert Scale

Score	Percentage of Improvement
7	≥75% improvement
6	≥50% improvement
5	≥25% improvement
4	0 (no change)
3	≥25% deterioration
2	≥50% deterioration
1	≥75% deterioration

PRF was performed in the operating room in an ambulatory setting according to a standard technique previously described by other authors.[10–12] The treatment was always applied immediately adjacent to the affected DRG for 120 seconds at a constant voltage (45 V) using a RFG 3C PLUS lesion generator (Radionics, Burlington, MA, U.S.A.). If necessary, voltage was constantly adjusted to keep the mean tip temperature at a maximum of 42°C. The pretreatment impedance, as assessed by the RFG 3C PLUS lesion generator, was controlled, and if necessary, saline was injected to reduce it to level below 450 ohms.

Analgesic efficacy of PRF was assessed using a 10-point Numeric Rating Scale (NRS) at specified time points including: prior to treatment (baseline), and at 30, 60, 90, and 180 days after treatment. The Global Perceived Effect (GPE) was assessed using a 7-point Likert scale (Table 1)[13] at 30, 60, 90, and 180 days after treatment. Reduction in medication use at the end of the study, as well as the number of complications associated with the technique, was analyzed for each of the three diagnostic groups.

PRF was repeated in those patients who, at second follow-up assessment (60 days), had an NRS score of >5, provided there had been an improvement of 50% or more at day 30. PRF was considered to be ineffective in those patients who did not achieve a decrease in NRS score of at least 2 points either on day 30 or on day 60. Repeat procedures were carried out at the same level as the initial treatment. Success was defined as a decrease in NRS score of 2 points and/or a GPE greater than 5.

Statistical Analysis

Two null hypotheses were tested. The first hypothesis tested was that PRF does not reduce pain. The second hypothesis tested was that the effect of PRF is similar in all three diagnostic groups. The NRS scores and the GPE, in all three diagnostic groups (intergroup), were compared using Kruskal–Wallis one-way ANOVA test-

ing, while the intragroup comparison of the changes in these two scores throughout the study period was tested using Friedman's nonparametric two-way ANOVA. When the groups were not homogeneous, the Mann–Whitney *U*-test was employed to compare quantitative variables in all groups. Fisher's test was used for nominal categorical variables owing to the small sample size of the study. A *P* value of less than 0.05 was considered to be statistically significant.

RESULTS

Demographic data grouped according to the diagnostic categories are provided in Table 2. Patients with SS were generally older; patients with FBSS had longer duration of symptoms prior to treatment. Mean NRS at baseline, 30 and 60 days and percentage of patients with GPE scores consistent with ≥50% improvement at 30 and 60 days are shown in Table 3. FBSS patients ($n = 13$) underwent a total of 19 procedures, HD patients ($n = 29$) had 39 procedures, whereas SS patients ($n = 12$) were given 17 treatments. All subjects were studied at the 30- and 60-day time points except three patients. Two patients from the HD group did not return for follow-up examination and a third patient from the SS group was referred to Orthopedics, in compliance with his own request. All three, per intention-to-treat analysis, were considered efficacy failures. The data for 90 and 180 days are treated separately, as patients who had unsuccessful treatment at 60 days were removed from study and offered alternative therapy (Table 4).

The percentages of patients with GPE scores of ≥6 after 60 days are shown in Table 4. There were no differences in the baseline NRS scores among the different diagnostic groups ($P = 0.90$). The NRS scores at 30 days ($P < 0.05$) and at 60 days ($P < 0.01$) were significantly higher in the FBSS group, with no differences between the HD and SS groups at any time point studied. A clinically and statistically significant decrease in the NRS score was observed in patients with HD ($P < 0.05$) and SS ($P < 0.001$), but not in those with FBSS. The percentage of patients who were successfully treated at each follow-up point is shown in Figure 1. Therapeutic success was defined as a GPE greater than 5 at 60-day follow-up (15.3% in FBSS, 66.6% in SS, and 72.4% in HD), or a decrease in NRS score of 2 points. According to these criteria, the NNT was 6.5 patients for FBSS, 1.49 for SS, and 1.38 for HD. The odds ratio for the

Table 2. Demographic Data

	HD	SS	FBSS
n	29	12	13
Male	17	3	6
Female	12	9	7
Mean age in years (range)	52.5 (34–85)	68.6 (39–81)	56.4 (33–77)
Mean time between onset and treatment in months (range)	25.8 (6–120)	17 (6–60)	44 (6–252)
Mean no. of procedures (range)	1.2 (1–3)	1.5 (1–3)	1.8 (1–4)
Treatment (WHO)			
WHO 1	12	5	1
WHO 2	14	6	7
WHO 3	3	1	5

FBSS, failed back surgery syndrome; HD, herniated disc; SS, spinal stenosis; WHO, World Health Organization Analgesic Ladder.

Table 3. Numeric Rating Scale (NRS) Scores (Mean ± SD) and Global Perceived Effect (GPE) Results up to Day 60

	HD	*n*	SS	*n*	FBSS	*n*
NRS						
Baseline	7 ± 1.30	27	6.9 ± 2.97	11	6.7 ± 2.07	13
30 days	3.04 ± 1.89	27	3.5 ± 2.85	11	5.6 ± 1.91	13
60 days	3.13 ± 2.13	25	2.7 ± 2.56	10	5.9 ± 1.84	13
GPE						
30 days	79.3% (71.7–86.9)		66.6% (59.9–73.3)		30.7% (18–43.4)	
60 days	72.4% (63.8–80.9)		66.6% (59.9–73.3)		15.3% (5.4–24.9)	

NRS score: 11-point NRS.
GPE results: percentages of patients with a GPE score ≥6.
FBSS, failed back surgery syndrome; HD, herniated disc; SS, spinal stenosis.

Table 4. Numeric Rating Scale (NRS) Scores (Mean ± SD) and Global Perceived Effect (GPE) Results after 60 Days

	HD	*n*	SS	*n*	FBSS	*n*
NRS score						
90 days	3 ± 1.93	21	2.8 ± 2.60	9	6.0 ± 2.69	6
180 days	2.6 ± 1.81	16	2.6 ± 2.92	8	—	—
GPE score						
90 days	51.7% (40.8–62.6)		58.3% (50,2–66.4)		15.3% (8–29.8)	
180 days	41.3% (29.1–53.5)		41.6% (24.3–58.9)		—	

NRS score: 11-point NRS.
GPE results: percentages of patients with a GPE score ≥6.
FBSS, failed back surgery syndrome; HD, herniated disc; SS, spinal stenosis.

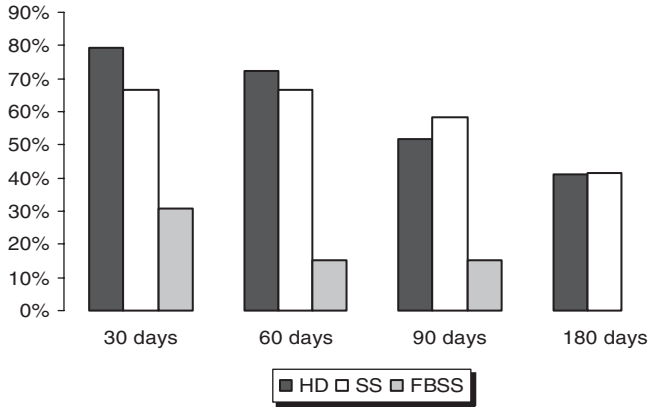

Figure 1. Percentage of patients successfully treated. FBSS, failed back surgery syndrome; HD, herniated disc; SS, spinal stenosis.

HD group vs. the FBSS group was 14.43 (95% CI: 2.6 to 80.03), and for the HD group vs. the SS group was 1.43 (95% CI: 0.30 to 5.59).

The need for medication was similarly reduced among those patients with HD (72.2%; 95% CI: 56% to 88.4%) and SS (83.3%; 95% CI: 62.2% to 99.9%), in contrast to the FBSS group, in which only 15.3% of the patients (95% CI: 0% to 34.7%) were able to reduce their need for medication. The percentage of patients who required no further medication treatment was significantly higher ($P < 0.05$) in the HD patients (41.3%; 95% CI: 23.5% to 59.1%) compared to those with SS (8.3%; 95% CI: 0% to 23%). None of the patients in the FBSS group was able to completely discontinue medication treatment. No complications directly attributable to PRF were observed and no patient required hospital admission.

DISCUSSION

Chronic LRP is an important medical and socioeconomic problem that affects 15% of the population.[14,15] Intervertebral disc herniation is the most common cause of LRP[16] followed by FBSS, an entity that affects 20% to 40% of the patients who undergo lumbar surgery each year,[17] and SS, a common cause of pain and functional limitations in the elderly.

Conservative therapies for these above ailments often fail.[18] When conservative therapies prove inadequate, invasive therapies may be tried including the epidural administration of corticosteroids. The level of evidence in managing LRP with epidural steroids is strong for short-term relief but limited for long-term relief.[19–23] However, the evidence is inconclusive in management SS. Reported complication rates of epidural steroid injection vary, ranging from 0% to 9.65%;[24] some of these complications are of very serious nature.[25,26] Selective radicular block appears to produce short-term improvement, but a subsequent rebound effect can develop.[27] A third therapeutic option is the transforaminal epidural block. The transforaminal approach is target specific, using the smallest volume of injectate possible to reach the primary site of pathology: the ventrolateral epidural space.[25,26,28] The evidence for this approach in lumbar nerve root pain because of HD is arguably strong for both short-term and long-term improvement. The evidence is only moderate in the management of LRP because of FBSS for both short- and long-term improvement, and is limited in the management of lumbar SS.[23]

Radiofrequency thermolesioning has been applied to the DRG at thoracic levels,[4] cervical levels,[3] and the lumbar spine.[5] Recently, there have been increasing numbers of reports using PRF at these targets.[9,29,30] If we compare our results with PRF in patients with FBSS with those of Erdine,[31] we observe striking differences. In contrast to our experience, in the aforementioned study, his study PRF produced significant improvement in 60% of patients at 6-month follow-up. In our retrospective series, patients with FBSS had predominant symptoms consistent with neuropathic leg pain (LRP), although this group can encompass several clinical etiologies having a mixture of nociceptive and neuropathic

components. The variability in the clinical presentations of these complex patients may be partially explanatory.

The study by van Zundert et al. examined PRF in the cervical region.[9] In this study, 72% of patients had greater than 50% improvement in pain at 2 months. This compares reasonably well with our findings (61%). As in the Van Zundert et al. study, we observed no cases of post-treatment neuritis or neurological complication. This finding is in sharp contrast to the post-treatment course seen with conventional RF, where transient but bothersome neuritis occurs frequently.[1–3] RFTC thermolesioning treatment caused burning pain in 60% of patients and hyposensitivity in the associated dermatome in 35% in the unblinded study by van Kleef et al.[1] These side effects were still present at 3 weeks but resolved spontaneously at 6 weeks. In a controlled study,[2] 77% of patients reported a vague burning sensation in the treated dermatome, which lasted for a mean of 17 days. Slappendel et al.[3] also noted neuritis in six of 32 and five of 29 patients, with cervical RFTC at 40°C and 67°C, respectively.

Radiofrequency thermolesioning is a well-documented treatment,[32–35] but it remains controversial in the presence of neurological lesions. The preexistence of a neurological lesion or neuropathic pain is often considered a contraindication to the use of thermocoagulation with RF.[9] The performance of a neuroablative procedure in the presence of a neural lesion may be inappropriate because of the possibility of either aggravating the preexisting disorder[8] or producing a denervation dysesthesia. The use of PRF could reduce or potentially even eliminate these risks associated with the use of thermocoagulation because PRF does not produce a clinically obvious neural lesion. PRF appears to have efficacy equivalent to RFTC thermolesioning.[6] However, to date, relatively few PRF patients have been studied long-term. Clearly, this assertion is largely based upon retrospective data and anecdotal reports. Randomized controlled trials are required before any claims can be made about its place in the therapeutic armamentarium.

Some methodological aspects of our study limit the conclusions. The data were collected retrospectively and the numbers of patients were relatively small. Consequently, the resultant confidence intervals were too wide to allow us to make predictions regarding individual patients. A controlled, prospective study may yield results with narrower confidence intervals. It can be predicted from our data that such a study will require a sizable number of patients with uniform etiology of pain. We conclude that, in our hands and with our patient population, PRF of DRG yields satisfactory results in patients with HD, and lesser but worthwhile results in patients with SS. PRF of DRG appears to be of no benefit to patients with FBSS.

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