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Original Research

Is Electrocatheter-Mediated High-Voltage Pulsed Radiofrequency of the Dorsal Root Ganglion an Effective Adjuvant to Epidural Adhesiolysis in the Treatment of Chronic Lumbosacral Radicular Pain? A Retrospective Analysis

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Abstract

This study aims to determine if high-voltage PRF could effectively adjunct epidural adhesiolysis (EA) in treating patients with chronic lumbosacral radiating pain (LSRP) and neuropathic characteristics. A total of 409 patients suffering from a single leg-radiating pain lasting for > six months and unresponsive to previous treatments were divided into three different groups: Group 1 consisted of 227 patients suffering from LSRP in lumbar stenosis, 84

treated with EA alone and 143 with PRF-EA; group 2 consisted of 99 patients suffering from LSRP in FBSS (Failed Back Surgery Syndrome), 24 treated with EA alone and 75 with PRF-EA; group 3 consisted of 83 patients suffering for LSRP in discal herniation, 20 treated with EA and 63 with PRF-EA. NRS evaluated the outcome at rest and in movement, SF-12 Physical and Mental Health Summary Scales, and present pain intensity scale (PPI), before the treatment and at the 1-month follow-up for all the patients included in the study. Descriptive statistics (mean ± SD) were reported for NRSrest, NRSmov, PPI, PCS, and MCS scores. A dependent sample T-test was used to compare pre and post-treatment outcome measures (NRS, PPI, PCS, MCS), in patients treated for discal herniation, FBSS and stenosis, respectively. A potential difference in outcome between the different procedures performed in the three groups (EA + PRF versus EA alone) was analyzed by applying an independent two-tailed t-test. P value less than 0.05 represented a significant difference. A significant reduction of radiating pain was observed at one-month follow-up in NRSrest and NRSmov, PPI scores, for all the three groups of patients, independently of the treatment adopted ($p < 0.001$). PCS12 and MCS12 significantly increased for all three groups of patients at 1-month follow-up ($p < 0.001$). No significant differences in outcome were detected for both procedures (EA vs. PRF-EA) in all three groups ($p > 0.05$). PRF and PRF-EA effectively reduce neuropathic pain intensity and improve the quality of life in patients who suffer from lumbosacral radiating pain in the context of lumbar stenosis, FBSS, or discal herniation. Adding pulsed radiofrequency (PRF) to epidural adhesiolysis alone does not improve the outcome.

Keywords
PRF; adhesiolysis; radiculopathy; chronic lumbosacral pain; NRS

1. Introduction

Over the past 30 years, epidural adhesiolysis was pioneered and refined by Racz and Heavner [1-3]. Later, McCarron [4] demonstrated that the nucleus pulposus is responsible for pro-inflammatory activity in the epidural space in dogs. In humans, chronic discal microstructural defects could result in frank annulus tears with the following extrusion of disc material in the epidural space. This process could be responsible for epidural adhesion formation and related pain [5]. Furthermore, the posterior longitudinal ligament is highly innervated and is essential to source back pain associated with epidural adhesions [6].

Multiple systematic reviews have summarized that the lysis procedure is now considered the first interventional treatment option for chronic lumbosacral radicular pain (CLSRP) [7, 8]. A recent randomized study assessed the long-term efficacy of lumbar epidural lysis of adhesions in patients with chronic radicular pain with a 10-year follow-up [9].

Although the medical literature agrees on the positive role of epidural adhesiolysis for CLSRP, insufficient evidence about pulsed radiofrequency stand-alone (PRF) efficacy has been reported, even poorer for PRF associated with EA, in the treatment of chronic radicular pain.

Pulsed radiofrequency (PRF) is a minimally neuro-destructive procedure used to treat pain disorders. Few randomized controlled trials on the PRF efficacy for CLSRP are available in the

medical Literature. Therefore, conclusions about PRF effectiveness are still debated, and guidelines about disorders that might benefit from the procedure are still lacking [10].

Hence, this study aims to determine if high-voltage PRF could effectively be an adjuvant of epidural adhesiolysis (EA) in treating patients with chronic lumbosacral radiating pain (LSRP).

2. Methods

This study was approved by the Institutional Review Board from Santa Maria Maddalena Hospital and the local ethical committee (Research Ethics Committee Reference Number 526CESC). The procedure and its potential harm were fully explained to the patients. Informed consent was obtained before each procedure.

2.1 Patients' Selection

Four hundred nine patients suffering from chronic leg pain (>6 months) and unresponsive to first-line medical treatments were divided into three groups: 227 patients suffering from LSRP in lumbar stenosis (group 1), 84 treated with EA alone, and 143 with PRF-EA; 99 patients suffering from LSRP in FBSS (Failed Back Surgery Syndrome) (group 2), 24 treated with EA alone and 75 with PRF-EA; 83 patients suffering for LSRP in discal herniation (group 3), 20 treated with EA and 63 with PRF-EA. The patients' assignment to a specific treatment was based on the presence of mono or pluriradicular pain. In the first case, the patient was placed in the PRF-EA group; in the second case in the EA group. All the procedures have been performed by three surgeons (MLG, GS, MZ) in the same institution. Exclusion criteria applied are the following: (I) a probable neuropathic pain, (II) clinical findings not consistent with MRI findings, (III) pain improvement after first-line therapy (such as NSAID use); (IV) patients suffering from central nervous system diseases or peripheral distal neuropathies, (V) psychiatric disorders, (VI) radiculopathies requiring urgent surgery (e.g., cauda equina syndrome), and (VII) reported allergy to anesthetics.

2.2 Outcome Measures

The outcome was evaluated by three different variables: the numeric rating scale (NRS) at rest and in movement; SF-12 Physical and Mental Health Summary Scales (in PCS and MCS scores); the present pain intensity scale (PPI). NRS for pain is an 11-point numeric scale evaluating the pain intensity in adults from 0 (no pain) to 10 (extreme pain) [11]. The SF-12 is a self-reported outcome measure assessing the impact of health on an individual's everyday life. Scores range from 0 to 100, with higher scores indicating better physical and mental health functioning. A score of 50 or less on the PCS-12 has been recommended as a cut-off to determine a physical condition, while a score of 42 or less on the MCS-12 may indicate clinical depression [12]. PPI is a short form of the McGill Pain Questionnaire: Patients were asked to rate their pain on the PPI index: 1 = no pain, 2 = mild, 3 = discomfort, 4 = distressing, 5 = horrible, and 6 = excruciating [13].

The outcome variables were evaluated at the moment of admission in our institution (before the treatment) and one-month follow-up during the post-hospital follow-up visit to our medical clinic.

2.3 Statistical Analysis

Statistical analysis was performed using SPSS version 23 (IBM Corp., Armonk, NY, USA).

Descriptive statistical analysis is presented as mean and standard deviation for continuous variables. After assessing the normal distribution of the data using the Shapiro-Wilk test, we applied the Dependent Samples T-test to compare pre-and post-treatment clinical scores (NRS, PPI, PCS, MCS), in patients treated for discal herniation, FBSS and stenosis, respectively.

Subsequently, we analyzed the potential difference in outcome between the different procedures performed in the three groups (EA + PRF versus EA alone) by applying an independent two-tailed t-test. P value less than 0.05 represented a significant difference.

2.4 Treatments

Every patient enrolled in this study was treated as follows: intravenous access was obtained, and an IV antibiotic was administered before the treatment; the patient was positioned prone on a fluoroscopy table. PRF was delivered through a multifunctional Cosman catheter, an X-ray guidable and flexible temperature-sensing electrode, and an injection port. Local anesthesia was administered and a cannula was inserted through the sacral hiatus. Under fluoroscopic guidance, the electrode was introduced through the needle placed into the lumbosacral epidural space and positioned close to the dorsal root ganglion of interest. This area corresponded to the dorsal–cranial quadrant of the intervertebral foramen on the lateral fluoroscopic image and midway into the pedicle column on the anteroposterior view. The catheter was connected to a generator (G4 System Cosman Medical Inc.) that delivered a 2-Hz motor stimulation with an output of up to 2 V to rule out any motor nerve damage and a 50-Hz sensory stimulation with an output current <0.6 V.

2.5 PRF-EA Group

Pulsed RF (PRF) is a process whereby short bursts of RF are delivered to a target nerve producing effects on signal transduction to reduce pain; this procedure does not produce a neural lesion, but a neuromodulation. PRF was started if impedance values were coherent with the epidural space (i.e., 200 to 400 Ω). Previous studies showed that delivering PRF by multiple cycles provided a better outcome [14, 15]. Therefore, each patient in this group received PRF for two cycles of 240 seconds each at a frequency of 2-Hz (20 ms of current and 480 ms without stimulation resulting in 2 active phases/second), the voltage between 65 and 80 V, and a tip temperature of 42°C. After 5 minutes, a 2 mL injection containing 0.25% of bupivacaine was delivered and, if no motor impairment occurred in the next 15 minutes, followed by the administration of 3 mL of the contrast medium iopamidol to observe the myelogram spreading to the nerve root of interest. The adhesiolysis was performed with the injection of hyaluronidase 900 units and 8 mg of betamethasone with a total volume of 5 mL.

2.6 EA Group

Adhesiolysis was performed with the injection of hyaluronidase 900 units and 8 mg of betamethasone with a total volume of 5 mL in the epidural space.

3. Results

The total patients' mean age was 68.86 ± 14.45 (22-93 years), with a clear prevalence of females to males (60.1% vs. 39.9%). The mean duration of complaints was 7.33 ± 4.05 months (range 6-23).

For more details on demographic data, refer to Table 1. A significant reduction of radiating pain was observed at 1-month follow-up in NRSrest and NRSmov, PPI scores, for all three groups of patients, independently of the treatment adopted ($p < 0.001$) [Figure 1, Table 2]. PCS12 and MCS12 significantly increased for all three groups of patients at 1-month follow-up ($p < 0.001$) [Figure 2, Figure 3; Table 2]. Table 3 reports all the detailed descriptive statistics data by treatment group and compares pre and post-treatment scores of different procedures within the groups. No significant differences in outcome were detected for both procedures (EA vs. PRF-EA) in all three groups ($p > 0.05$) [16].

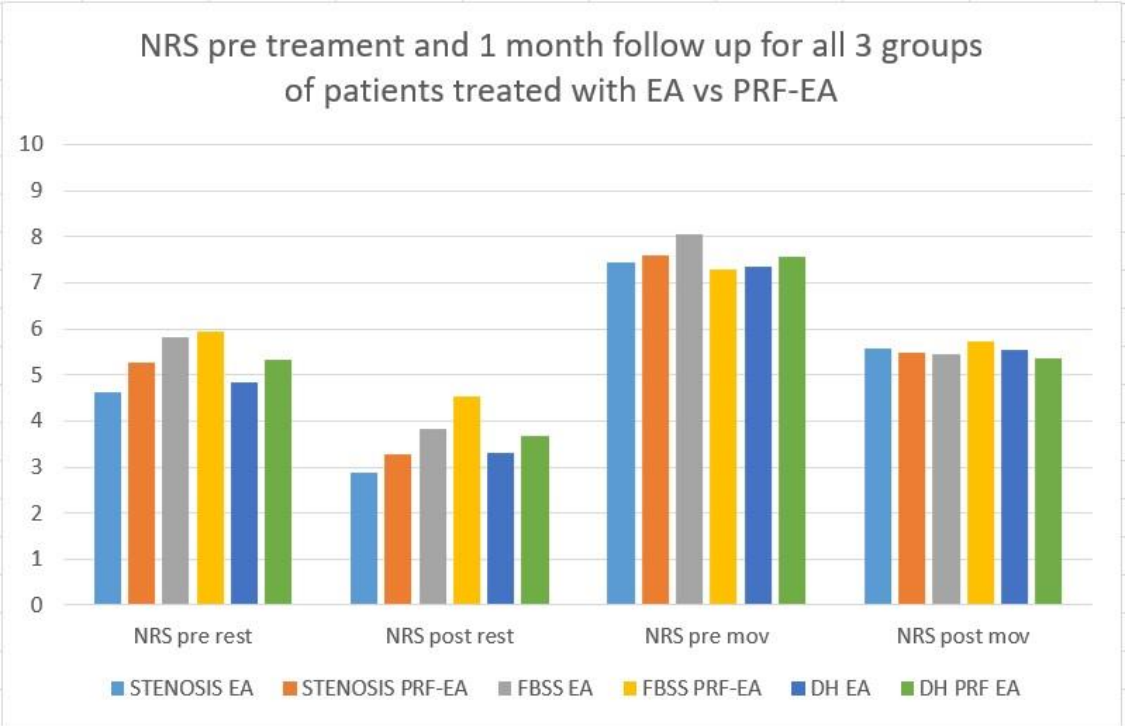

Figure 1 NRS pre treatment and 1 month follow up for all three groups of patients treated with EA vs PRF-EA.

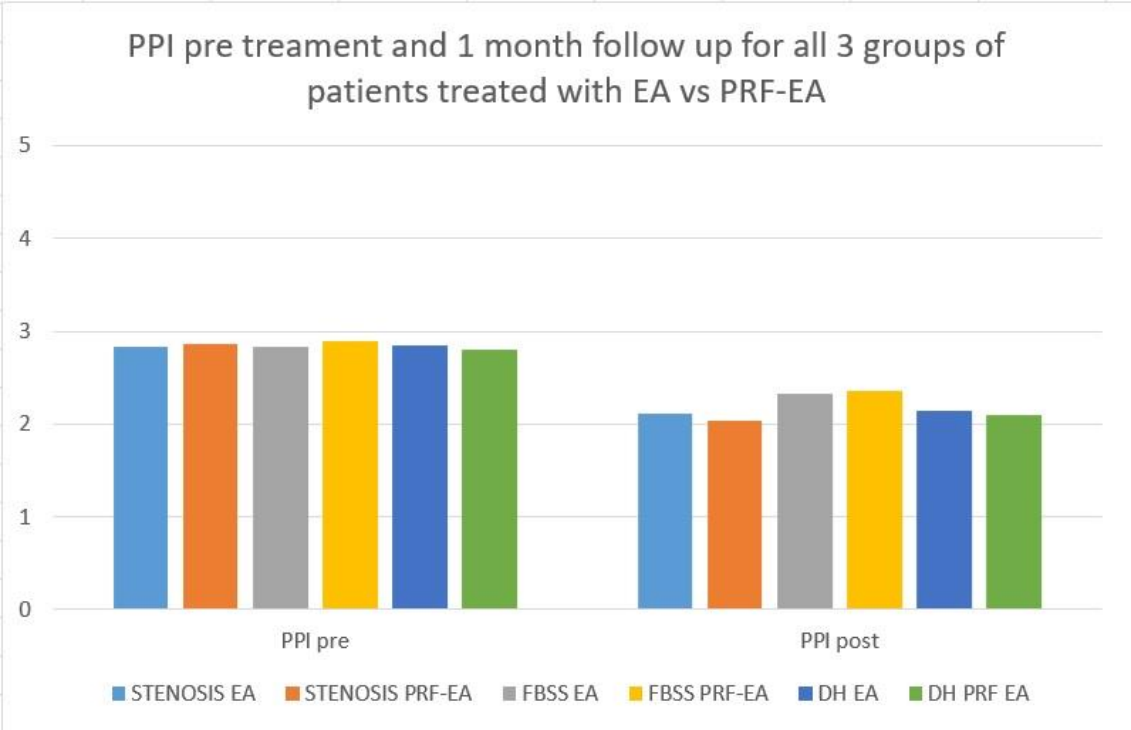

Figure 2 PPI pre treatment and 1 month follow up for all three groups of patients treated with EA vs PRF-EA.

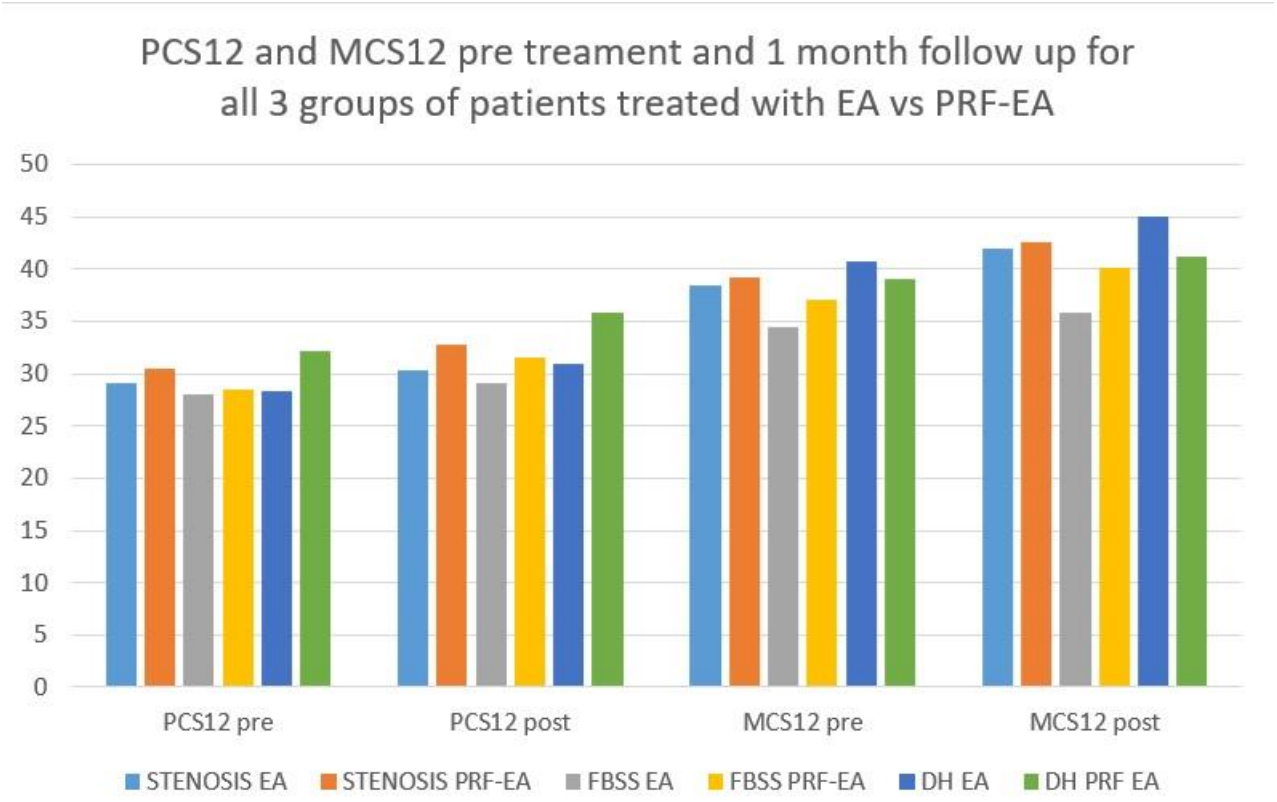

Figure 3 PCS12 and MCS12 pre treatment and 1 month follow up for all three groups of patients treated with EA vs PRF-EA.

Table 1 Demographic data.

	Group 1 – Lumbar stenosis		Group 2-FBSS		Group 3 – Discal herniation	
	EA	PRF-EA	EA	PRF-EA	EA	PRF-EA
Number of patients enrolled	84	143	24	75	20	63
Age (years)	71.76 ± 15.37	69.40 ± 15.89	69.27 ± 12.43	69.40 ± 12.97	66.93 ± 15.27	66.40 ± 14.79
Female	58.9%	74.4%	69.2%	62.9%	61.6%	58.6%
Male	41.1%	25.6%	30.8%	37.1%	38.4%	41.4%
Duration of complaints (months)	7.30 ± 1.30	9.51 ± 4.93	9.10 ± 5.12	9.58 ± 5.02	8.94 ± 3.92	9.53 ± 4.97

Data for age and duration of complaints are mean ±SD.

EA, epidural adhesiolysis; PRF-EA, pulsed radiofrequency and epidural adhesiolysis; FBSS: failed back surgery syndrome.

Table 2 Pre and post-treatment outcomes in pain scores in groups 1. 2 and 3.

	Group 1 – Lumbar stenosis			Group 2-FBSS			Group 3 – Discal herniation		
Score	pre-treatment	post-treatment	P	pre-treatment	post-treatment	P	pre-treatment	post-treatment	P
NRS at rest	5.02 ± 2.91	3.13 ± 2.60	<0.001	5.92 ± 2.75	4.36 ± 2.86	<0.001	5.27 ± 2.54	3.62 ± 2.77	<0.001
NRS at movement	7.52 ± 2.02	5.51 ± 2.61	<0.001	7.47 ± 2.05	5.67 ± 2.63	<0.001	7.54 ± 1.75	5.41 ± 275	<0.001
PPI	2.85 ± 0.86	2.07 ± 1.18	<0.001	2.88 ± 0.90	2.35 ± 1.18	<0.001	2.78 ± 0.77	2.13 ± 1.11	<0.001
PCS	29.94 ± 6.65	31.85 ± 6.79	<0.001	28.3 ± 6.32	30.96 ± 6.87	<0.001	31.18 ± 7.07	34.4 ± 8.82	<0.001
MCS	38.90 ± 10.35	42.31 ± 10.66	0.042	36.39 ± 9.55	39.10 ± 10.72	0.015	39.60 ± 9.18	42.08 ± 10.11	0.042

Data are mean ± standard deviation.

NRS: Numeric Rating Scale; PPI: Pain Intensity Scale; PCS: Physical Health Summary Scale; MCS: Mental Health Summary Scale.

Table 3 Comparison of pre and post treatment scores of different procedures within the groups.

	Group 1 – Lumbar stenosis			Group 2-FBSS			Group 3 – Discal herniation		
	EA	PRF-EA	p	EA	PRF-EA	p	EA	PRF-EA	p
NRS pre rest	4.62 (2.78)	5.26 (2.96)	0.533	5.83 (3.08)	5.95 (2.65)	0.371	4.85 (2.87)	5.34 (2.40)	0.753
NRS post rest	2.88 (2.62)	2.28 (2.58)		3.83 (3.10)	4.53 (2.78)		3.30 (2.88)	3.67 (2.73)	
NRS pre mov	7.43 (1.77)	7.58 (2.15)	0.470	8.04 (1.85)	7.29 (2.09)	0.095	7.35 (2.15)	7.56 (1.61)	0.525
NRS post mov	5.57 (2.77)	5.47 2.52)		5.46 (2.71)	5.73 (2.62)		5.55 (2.83)	5.36 (2.75)	
PPI pre	2.83 (0.78)	2.86 (0.90)	0.593	2.83 (1.09)	2.89 (0.84)	0.896	2.85 (0.33)	2.80 (0.62)	0.914
PPI post	2.11 (0.78)	2.04 (1.18)		2.33 (1.40)	2.36 (1.11)		2.15 (1.13)	2.10 (1.12)	
PCS pre	29.11 (6.39)	30.43 (6.77)	0.217	27.97 (5.40)	28.40 (6.62)	0.181	28.39 (4.54)	32.24 (7.36)	0.607
PCS post	30.27 (6.79)	32.76 (6.64)		29.44 (8.60)	31.50 (6.90)		30.82 (8.13)	35.86 (8.66)	
MCS pre	38.43 (10.29)	39.17 (10.41)	0.923	34.40 (8.36)	37.03 (9.86)	0.535	40.80 (9.57)	38.99 (9.06)	0.425
MCS post	41.91 (11.05)	42.51 (10.48)		35.90 (9.53)	40.12 (10.82)		44.97 (10.43)	41.22 (9.33)	

Data are mean (SD).

EA. Epidural adhesiolysis; NRS. Numeric Rating Scale (rest = at rest; mov = in movement; pre = pretreatment; post = post treatment at 1 month follow up) PRF-EA. Pulsed radiofrequency and epidural adhesiolysis; PCS & MCS. Physical and Mental Health Summary Scales. PPI. Pain intensity scale.

4. Discussion

The results of this study emphasize that there is no therapeutical impact in the adjunction of high-voltage PRF to EA in the treatment of CLSRP at a one-month follow-up. All the patients considered in our three groups division suffered from CLSRP due to lumbar stenosis (Group 1), radiculopathy in FBSS (Group 2), or radiculopathy in the discal hernia (Group 3). All the patients improved their clinical condition at 1-month follow-up independently of the treatment adopted (EA alone vs. EA + PRF).

The last decade's medical literature considers EA the first Interventional treatment option for chronic lumbosacral radicular pain (CLSRP) [7, 8]. One consistent randomized controlled trial of EA vs. placebo in treating CLSRP demonstrated the long-term efficacy of lumbar epidural lysis of adhesions in patients with chronic radicular pain with a 10-year follow-up [9].

Many RCT studies, as displayed by Farì et al. [17] in their meta-analysis, demonstrated that both pulsed or continuous or water-cooled RF (WCRF), could represent a promising therapy for treating chronic musculoskeletal pain, especially when other approaches are ineffective or not practicable. Their group also showed that continuous RF combined with therapeutic exercise in rehabilitating severe hip osteoarthritis is an attractive option for significant pain relief as it allows patients to carry out kinesitherapy more easily [18].

The available studies on pulsed radiofrequency applied to CLSRP are mostly needle-mediated, with only one prospective case series performed with a multifunctional electrode. Furthermore, heterogeneous inclusion criteria, devices, and protocols adopted yielded controversial results [19-23].

Effects of Pulsed radio frequency were evaluated by Van Zundert et al. on cervical, dorsal, and lumbar radiculopathies compared with two other treatment modalities: transforaminal epidural steroid injection (TFESI) and sham stimulation. This study concluded that patients suffering from cervicobrachial pain had a better outcome than those with CLRP if treated with PRF [24, 25].

The results of O'Gara et al. also confirmed the results of this latter study: their retrospective study found that the most significant pain relief after PRF in patients suffering from cervicobrachial pain was obtained more than six months after the procedure [20]. Moreover, several studies also demonstrate that the PRF duration effect in chronic pain is shorter than conventional radiofrequency, but no neurological complications are reported with PRF [16].

Except in one study [19], the follow-up period never exceeded six months in all the trials. Reports of PRF safety were satisfactory with primarily minor adverse effects, such as headache or post-procedure pain.

The results presented in this study could appear in severe contrast with the founding of Vigneri et al. [10]. In their randomized controlled trial, they showed the effectiveness of adding high-voltage PRF to EA in treating neuropathic pain due to chronic lumbosacral radiculopathy. We believe two limitations of our study could justify the differences found: firstly, the presence of neuropathic features was not investigated, while inclusion criteria were based only on the presence of radicular radiating pain, not discriminating between neuropathic, nociceptive, or mixed pain; secondly, follow up was restricted at one month (previous RCT study considered follow-up at six months) [16]. O'Gara et al. and Vigneri et al. show that the most significant pain relief is obtained after six months of PRF.

5. Conclusion

Our study is real-life-based and reports some results of our pain therapy department on a consistent number of patients in one year. Despite our study limitations, we believe that PRF and PRF-EA effectively reduce radicular pain intensity and improve life quality in patients suffering from lumbosacral radiating pain in the context of lumbar stenosis, FBSS, or discal herniation. After a one-month follow-up, adding pulsed radiofrequency (PRF) to epidural adhesiolysis alone does not improve the outcome. These results deviate from previous RCT studies [10] showing improved pain scores in groups where PRF was added to EA.

Abbreviations

EA	epidural adhesiolysis
PRF-EA	pulsed radiofrequency and epidural adhesiolysis
CLSRP	chronic lumbosacral pain
PCS & MCS	Physical and Mental Health Summary Scales
PPI	pain intensity scale
LBP	low back pain
FBSS	Failed Back Surgery Syndrome

Author Contributions

MLG, GS, MZ: contribution to the concept or design of the article; contribution to the acquisition, analysis, or interpretation of data for the article. AM: contribution to the concept or design of the article; contribution to the acquisition, analysis, or interpretation of data for the article. IG, SV: analysis, or interpretation of data for the article, Drafted the article or revised it critically for important intellectual content. AM: Drafted the article or revised it critically for important intellectual content. VP: Drafted the article or revised it critically for important intellectual content. CB, GP: Approved the version to be published.

Competing Interests

None.

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