Retrospective Study

Pulsed Radiofrequency Therapy at Different Voltages on Dorsal Root Ganglia Using Multifunctional Catheter to Treat Low Back Pain: A Comparative Retrospective Study

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Background: Applying pulsed radiofrequency (PRF) to the dorsal root ganglion (DRG) is an electrical neuromodulation technique, a valid complementary therapeutic treatment for failed back surgery syndrome (FBBS). Peridurolysis, when applied to vertebral canal adhesions, can be performed with dedicated catheters, providing patients with the benefits of mechanical, electrical, and pharmacological techniques.

Objectives: The aim of this study was to evaluate PRF's effects on the DRG as part of FBSS treatment at different follow-up times, comparing 2 groups of patients exposed to distinct levels of voltage (100 V vs. 45 V) from a PRF generator.

Study Design: A retrospective observational study was performed.

Setting: The study was conducted on a sample of patients from an Italian hospital.

Methods: PRF's effects on the DRG as part of FBSS treatment were evaluated through the Numeric Rating Scale (NRS) and the monitoring of 155 patients' opioid consumption at 3, 6, and 9 months. A Cosman® G4 model PRF generator was used. During follow-up periods, the Friedman test was applied to detect differences in outcomes between the 2 groups of patients, who were treated with different levels of voltage.

Results: The most frequent diagnosis (61.29%) was FBBS in patients at a mean age of 64 (± 11.8) years old. All patients were treated with PRF on the dorsal ganglion, with the addition of a drug mixture. Most were treated with 100 V (62%). A statistically significant decrease ($P < 0.001$) in the NRS score emerged both as a whole and in the 2 distinct groups. Moreover, the group of 100 V patients showed a significant ($P = 0.0360$) reduction in the use of opioids.

Limitations: This observational retrospective study was based on a convenience sampling that involved a limited number of patients.

Conclusions: E-field technology is the only way to generate a constant 38°/42° PRF and 100 V level throughout surgical interventions (respecting the exposure times "set" by the operator). The patient will not feel any pain or electric current because the generated milliamperes will be greatly reduced.

Key words: Pulsed radiofrequency, dorsal root ganglion, different voltage, high voltage, Cosman G4 PRF generator, e-field, failed back surgery syndrome, neuromodulation, peridurolysis

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In 2020 the International Association for the Study of Pain (IASP) proposed a new definition of pain: "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (1), based on a subjective experience that may affect the individual's social and psychological well-being.

Chronic pain (recurring for more than 3 months) affects 20% of people worldwide. One valid treatment for chronic pain is the radiofrequency ablation (RFA) technique, which Shealy introduced in 1975 (2). RFA was created as a detrimental analgesic technique that consisted of supplying current through an electrode needle with an active tip. Originally, RFA was meant to monitor the temperature of the lesion and not of the voltage so the neuromodulation would be reversible (3). However, the need for a nonharmful RF focused on neuromodulation rather than the injury of specific nervous structures was eventually recognized (4).

A new application of RFA that avoids the tissue damage caused by a rising temperature (5) is pulsed radiofrequency (PRF), which appears less destructive than the classic continuous radiofrequency (RF) techniques (6,7). The uniquely "lesive" phase of RF has seen the rise of a new school of thought, one aimed at evaluating a signal modulation and not a definitive interruption of the signal. In 1965, physicians started to understand that the size of the active part of a needle (active tip) from which the RF was applied affected the size and therefore the volume of the electric field generated and the resulting damage to the area (8). The concept of neuromodulation consistently took shape in a way that allowed physicians to analyze the effects of the electrical parameters applied to the nervous tissue.

Later, the interest in applying PRF to the dorsal root ganglion (DRG) began to grow; particular attention was given to electrical conduction applied to human anatomical structures and the resulting potential problems with the bioelectrical field (9). In particular, PRF on the DRG is an electrical neuromodulation technique that represents a complementary therapeutic treatment of failed back surgery syndrome (FBSS), defined as "a persistent or recurrent pain, mainly in the region of the lower back and legs, even after technically, anatomically successful lumbosacral spine surgeries" (10).

PRF on the DRG, mostly lumbar and irradiated to the lower limbs, is associated with the percutaneous decompressive adhesiolysis procedure of the fibrotic/adherent components in the vertebral canal and is sometimes the main cause of etiopathogenesis pain.

The peridurolysis applied to vertebral canal adhesions can be performed with physical techniques (using a catheter) or mechanical, electrical, and pharmacological ones. Mechanical adhesiolysis is basically functional to the catheter used. Starting from the need to correctly diagnose the patient, PRF is a safe technique and can be done without any complications. In fact, PRF produces long-term relief (of spinal pain) without thermal ablation because the high-voltage electric field reaches a maximum of 42 degrees Celsius (11-13).

The aim of this study is to evaluate the effects of PRF on the DRG as part of failed back surgery syndrome (FBSS) treatment at different follow-up points, comparing 2 groups of patients exposed to different levels of voltage (100 V and 45 V) from a PRF generator and highlighting the results associated with the highest voltage.

Methods

A retrospective observational study was performed, collecting a convenience sample of patients from a hospital database for a period of over 61 months. In particular, the data included the evaluation of pain on the Numeric Rating Scale (NRS): a rating scale of patients' self-reported pain intensity spanning from 0 (no pain) to 10 (worst pain imaginable). Accordingly, pain intensity was classified as mild (1-4), moderate (5-6), or severe (7-10), and patients' opioid consumption was recorded at 3, 6, and 9 months.

Adult patients (≥ 18 years old) who finished the follow-up with a complete medical chart and an NRS greater than 5 despite more than a month of opioid therapy were included in the sample. The study also excluded patients with coagulation disorders, current systemic infections, or major psychiatric illnesses.

The recruited patients were classified according to the type of voltage applied to the PRF generator. They were split into 2 groups: the patients in the first were treated with 45 V, and the patients in the second were treated with 100 V.

Each patient's therapeutic path was homogeneous: all underwent the same procedure, with the same technique and the same RF bipolar catheter; all the patients received the same mixture of drugs to perform the pharmacological peridurolysis (triamcinolone 40 mg and hyaluronidase 900 IU). The parameters used were 50 Hz for sensory stimulation and 2 Hz for motor stimulation. The PRF treatment was performed with the following parameters: temperature of 42°C, 100 or 45 V, 2 Hz, 20 ms for 15 minutes at the treated site.

The protocol was approved by the Institutional Review Board from San Vito al Tagliamento Hospital (Italy). This study was conducted according to the Declaration of Helsinki, and written informed consent was obtained from every patient before the treatment.

PRF Treatments' Equipment and Methods

A Cosman® G4 model PRF generator with multiple outputs for simultaneous PRF applications on multiple targets, a choice of bipolar or double bipolar technique, and relative monitoring of individual temperatures was used. This generator allowed the operator to set the sensory-motor stimulation values through automatic pulse control, optimizing the nerve's exposure to the electric field. The average impedance was set between 330 and 350 Ohm.

To maximize the benefits the generator's output could provide, we decided to use a bipolar device that let the electric field be as concentrated as possible on the anatomical target, avoiding potential interference with other implantable devices active on the patient (e.g., a pacemaker).

The bipolar catheter, certified for LisiJect RF ++ peridurolysis, had an introducer needle-cannula armed with a double mandrel: the first (made from medical steel) was used for difficult access, and the second (made from the radiopaque material tungsten, with a blunt tip for reaching the ideal site) for the introduction of the catheter (Figs. 1-3). The kit was equipped with several preformed nitinol stylets, both for navigating the epidural space and for the mechanical unblocking of adhesions.

This type of catheter had a thermocouple/probe suitable for motor and sensory stimulation (2 Hz/50 Hz) and PRF conduction with tip temperature monitoring. During the study, the bipolar catheter was introduced by the sacral hiatus approach, using the aforementioned introducer needle with an armed flexible cannula.

To check the peridural space, 75 mg of Jopamiro was administered, and a lateral-lateral (L-L) radiological imaging test was performed. Then, through radiological guidance, the stiffener mandrel was removed, and the nitinol mandrel (which was curved) was introduced. The catheter used had a block valve and an infusion path with 4 distal slots for drug infusions.

In cases of multilevel therapy, as the PRF procedure at the level of the most rostral metamer ended, the curved mandrel was removed, and the serpentine mandrel (Snake, Ercolina®) was introduced exclusively through radiological guidance. Afterward, the Snake mandrel and then the introducer needle were removed. During the retraction, the Snake performed a mechanical lysis of the adhesions, detaching them.

The neuromodulation treatment involves the application of RF to the root and ganglion region of cranial and peripheral nerves. In this way, the pain transmitted by the nerve is reset; the pain relief is evaluated and monitored throughout the medium and long term (over 6 months).

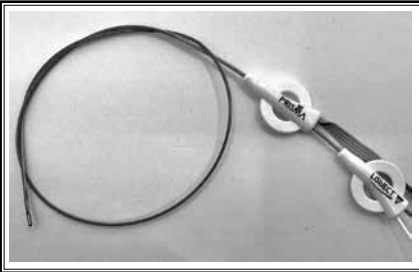

Fig. 1. *Multifunction bipolar radiofrequency catheter for epidurolysis.*

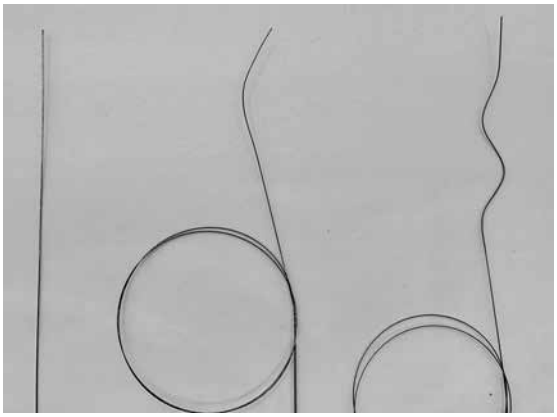

Fig. 2. *Curved mandrel and "snake" mandrel, both made of Nitinol*, to be introduced into the LisiJect RF++ catheter to direct it (curved) or to increase the mechanical lysis area, at the end of radiofrequency treatment (snake).*
*Nitinol maintains the original curvature of the mandrel (even if mechanically stressed) without losing the catheter's thrust force.

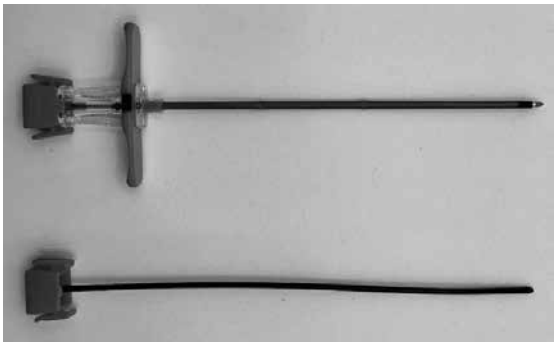

Fig. 3. *Preloaded introducer with rigid steel mandrel; the second one is a tungsten mandrel, dedicated to the final positioning of the introducer.*

If necessary, the infusion-based drug therapies can be repeated on patients who have already undergone them and experienced modest relief. In both groups of patients, the DRG RF procedure was conducted for 15 minutes, using the same method.

Statistical Analysis

A descriptive analysis of the sample was performed using frequencies for categorical variables and measurements of central tendency and dispersion for continuous variables. The differences between groups at each follow-up were evaluated using the Wilcoxon Mann-Whitney test. The Friedman test (nonparametric repeated measures ANOVA) was used to detect how the 2 patient groups' outcomes differed over the time spanning the pre-treatment period to the following 9 months.

The significance level for all tests was set to α = 0.05. All the analyses were performed using SAS 9.4 software for Windows (SAS Institute Inc.).

Results

A sample of 155 patients who would undergo the DRG RF procedure was selected from the hospital database. Most patients were women (61%), and their ages varied between 36 and 87 years old (mean age: 64 ± 11.8 years). All the patients were admitted to the hospital for one night.

The most frequent diagnosis was FBBS (61.29%), followed by arthrosis (27.10%); obliterating arteriopathy of the lower limbs (OALL) diagnoses (3.23%) and other pathologies were also found (Table 1). Mixed symptoms of radicular and axial low back pain were diagnosed in the patients; therefore, both nociceptive and neuropathic components were observed. All patients were treated with PRF on their dorsal ganglia, and the therapy used a drug mixture suitable for treating the adhesions.

The patients were therefore separated into 2 different groups based on the voltage of the generator used in the PRF treatment. The majority were treated with 100 V (62%); the rest received 45 V. No statistical differences were observed between the 2 groups in age, gender, or diagnosis (Table 1).

The outcomes (the NRS parameter and the consumption of opioids) were assessed separately at each follow-up and were used as indicators of the treatment's efficacy, both in the whole sample and in the 2 groups of patients.

NRS Evaluation

The NRS outcome of the whole sample decreased from the beginning of the treatment (6.2) to the ninth month afterward (0.7). The same reduction was also observed in the 2 groups: from 6.1 to 0.9 in the patients treated with 100 V and from 6.3 to 0.6 in the other group.

At each follow-up, the NRS parameter did not differ significantly between the groups ($P > 0.05$) (Table 2). Instead, a statistically significant decrease ($P < 0.001$) of the previously measured outcome emerged during the follow-up period, both as a whole and within the groups, considering the nonparametric repeated measures analysis (Fig. 4). No difference

Table 1. *Description of the 155 patients who underwent DRG PRF.*

	All Patients (n = 155)	Patients Who Received 100V (n = 96)	Patients Who Received 45V (n = 59)	*P* value
Age (mean ± SD)	64.4 ± 11.8	64.7 ± 11.3	63.8 ± 12.7	0.73
Women (n (%))	94 (61)	54 (57.4)	40 (42.6)	0.15
Etiopathogenesis of the Pain (n (%))				0.12
Leg Amputation	2 (1.3)		2 (3.4)	
Obliterating Arteriopathy of the Lower Limbs (OALL)	5 (3.2)	3 (3.1)	2 (3.4)	
Arthrosis	42 (27.1)	25 (26.1)	17 (28.8)	
Chronic Pelvic Pain	3 (1.9)	1 (1.0)	2 (3.4)	
Upper Back Pain	1 (0.7)	1 (1.0)		
Failed Back Surgery Syndrome (FBSS)	95 (61.3)	62 (64.7)	33 (55.9)	
Post-Herpetic Neuropathy	2 (1.3)	1 (1.0)	1 (1.7)	
Neuropathic Lower Limb Pain	2 (1.3)		2 (3.4)	
Missing	3 (1.9)	3 (3.1)	-	

Table 2. *NRS at each follow-up period, in the whole sample and in the 2 groups of patients (100 V and 45 V, respectively).*

Follow-Up	All Patients (n = 155)				Patients Who Received 100V (n = 96)				Patients Who Received 45V (n = 59)				WMW test
	Mean	SD	Median	IQR	Mean	SD	Median	IQR	Mean	SD	Median	IQR	P value
nrs_T1	6.2	2.1	6	4	6.1	2.0	6	4	6.3	2.2	6	4	0.57
nrs_T2	3.3	2.1	3	3	3.5	2.1	3	3	3.1	2.2	2	4	0.23
nrs_T3	1.2	1.5	1	2	1.5	1.6	1	2	1	1.2	1	2	0.14
nrs_T4	0.7	1	0	2	0.9	1.1	0	2	0.6	0.9	0	1	0.23

Follow-up period: T1 = pre-treatment; T2 = 3 months after treatment; T3 = 6 months after treatment; T4 = 9 months after treatment.

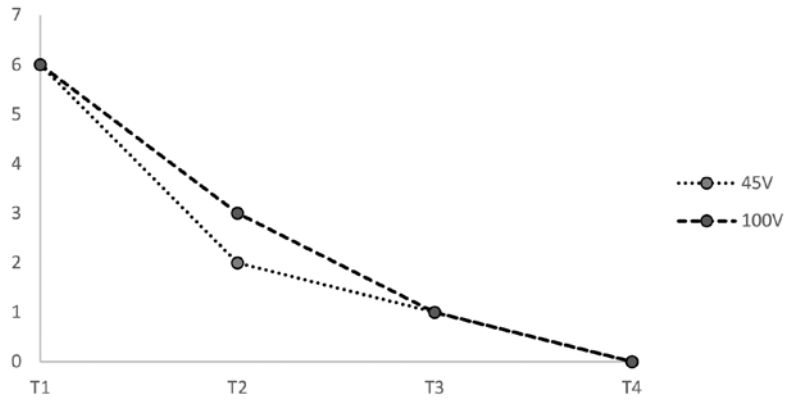

Fig. 4. *NRS trends (median values) at each follow-up period. T1 = pre-treatment; T2 = 3 months after treatment; T3 = 6 months after treatment; T4 = 9 months after treatment. Values shown are for each group (patients who received 100 V and 45 V, respectively).*

between the groups was highlighted in the analysis ($P = 0.1464$).

Opioid Consumption Evaluation

Results regarding the administered opioid dose were like those found in the NRS evaluation: no follow-up point revealed a significant difference ($P > 0.05$) between the values associated with different voltages (Table 3). However, in the analysis, the group of 100 V patients showed a significant ($P = 0.0360$) reduction in the use of opioids (Fig. 5), which differed from the 45 V group.

Patients' Satisfaction Evaluation

At the end of the follow-up period, patients' satisfaction was evaluated. This value was measured using a 4-point scale, varying from very dissatisfied (1) to very satisfied (4). Most of the patients in the sample (about 70%) were very satisfied, and only 3 patients in the 45 V group declared disappointment (very dissatisfied) with the received treatment. However, no significant difference emerged in the evaluation of the 2 groups ($P = 0.22$).

Discussion

FBSS is the most common complication of the surgical treatment of lower back pain, and this problem's incidence varies from 10 to 40% (14). PRF is an alternative treatment to FBSS and has lower rates of associated complications (15). As highlighted by some authors, the PRF treatment has presented many advantages in animals (13,16). In humans, PRF is also a safer procedure that reduces the risk of tissue damage and presents a less invasive alternative to surgical intervention. PRF allows the patient to experience similar outcomes to spinal surgery, as concluded by Trinidad et al (2015), who observed that after RF treatment, 80% of patients rejected spinal surgery in the short term, 76% rejected it in the long term, and all patients reported a high level of satisfaction (15). Furthermore, Van Boxem et al (17) demonstrated better results in patients who received PRF in the DRG. Those patients were aged around 50 years old and had a limited degree of disability.

The patients in our study's sample were aged between 36 and 87 years old and presented mild diseases without substantive functional limitations. The latter status is known as class II in the American Society of Anesthesiologists (ASA) physical status classification system.

Table 3. *Opioid consumption at each follow-up, in the whole sample and in the two groups of patients (100 V and 45 V, respectively).*

Follow-Up	All Patients (n = 155)				Patients Who Received 100V (n = 96)				Patients Who Received 45V (n = 59)				WMW Test
	Mean	SD	Median	IQR	Mean	SD	Median	IQR	Mean	SD	Median	IQR	*P* value
opp_morf_T1	25.3	27.9	20	40	26.5	25	20	40	23.4	32.1	10	25	0.24
opp_morf_T2	14.1	18.2	10	20	14.6	18.8	10	20	13.4	17.6	5	20	0.88
opp_morf_T3	5.7	8.8	5	10	6	7.2	5	10	5.4	10.6	0	5	0.24
opp_morf_T4	4.3	8.8	0	5	4.3	6.6	0	10	4.4	10.8	0	5	0.34

Follow-up period: T1 = pre-treatment; T2 = 3 months after treatment; T3 = 6 months after treatment; T4 = 9 months after treatment.

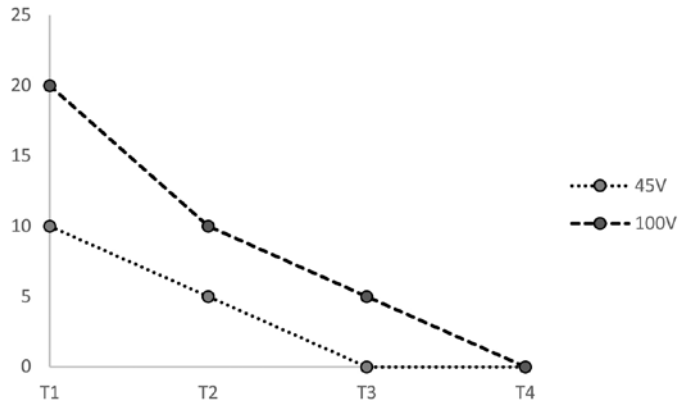

Fig. 5. *Opioid consumption trend (median values) at each follow-up period. T1 = pre-treatment; T2 = 3 months after treatment; T3 = 6 months after treatment; T4 = 9 months after treatment. Values shown are for each group (patients who received 100 V and 45 V, respectively).*

As observed in other studies, the measurements of the treatment's efficacy were based on quantitative and qualitative indicators such as NRS scores, drug consumption during the treatment, and personal evaluation of each patient's satisfaction level at the end of the therapy.

Although no significant results were found with DRG PRF, other authors' findings suggest PRF treatment is a useful alternative to surgery, observing significant decreases in NRS scores, reduced use of analgesics, and an association with a significant level of personal satisfaction (15). Our results reflect this description. Decreases in important indicators were found from the beginning of the DRG PRF treatment to 9 months after its end. In particular, patients' consumption of opioid drugs registered a statistically significant decrease not only within the follow-up period but also between the groups studied. These findings suggest the relevance of the equipment and the voltage of the generator involved in PRF treatments.

Meanwhile, new RF generators can benefit from a function called e-field. The e-field function is an automatic control of pulse settings that optimizes the exposure of nerve tissue to the electric field. This effect allows the physician to keep the temperature and voltage stable (> 45 V) during the treatment. In this way, a pulsed, monopolar, or bipolar RF is generated, keeping both the temperature and the voltage (tending to 100 V) constant throughout the intervention. Notably, the effects of PRF are based not on temperature but on the electric field, and the only way to increase the electric field and therefore the effectiveness of PRF is by raising the voltage.

Conclusion

With e-field technology and high-voltage PRF under 100 V, the patient will not feel any pain or electric current because the generated milliamperes will be greatly reduced. Exposing a nervous tissue to an electric field (without creating discomfort for the patient) during PRF while maintaining at least 45 V, 42°C, and a constant exposure time (T) is achievable only by applying a high voltage through an e-field algorithm.

High-voltage PRF could be a safe and promising therapy, and further studies should investigate the use of higher voltage in the treatment of several nervous clinical diseases. Therefore, although this is an obser-

vational retrospective study based on a convenience sampling of a limited number of patients, the results found may be a starting point for future investigations into higher-voltage e-field technology.

Author Contributions

PN and DR designed the study; PN, GG, and LP collected and analyzed the data. PN and CAC revised the paper.

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