

Original Article

Would Pulsed Radiofrequency applied to different anatomical regions have effective results for chronic pain treatment?

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Abstract

Objective: To observe the effect of Pulsed radiofrequency on patients presenting with complaints of chronic pain.

Methods: It was a retrospective cross sectional study which included patients with chronic pain who did not respond to conventional treatment. The study was conducted at the Pain Management Centre, Dicle University, Diyarbakir, Turkey from October 2008 to September 2010. The applications of Pulsed radiofrequency (PRF) were made under the guidance of C-arm fluoroscopy, local anaesthesia, and sedoanalgesia. The intervention types applied consisted of sacroiliac intraarticular, heel, sciatic nerve and impar ganglion Pulsed radiofrequency. Visual Analogue Scale (VAS) was used for pain assessment. Sacroiliac intraarticular PRF was applied to nine patients, impar ganglion PRF to eight patients, heel PRF to four patients and sciatic nerve PRF was applied to three patients.

Results: The mean age of the patients was 41.3±16.9 (range 15-77) years, 15 (62.5%) were females. The mean follow-up period was 8.5±5.4 months. A minimum 50% decrease was determined in the VAS scores of 16 (66.7%) patients compared to the initial values. The patients who had ≥ 50% decrease in their VAS scores in the sacroiliac group was 55.6. This value was 75.0, 75.0 and 66.7 in the impar, heel and sciatic nerve groups respectively. No early- or late-term complications were observed in any of the patients.

Conclusions: Pulsed Radiofrequency implementation was found to be an effective and safe method for chronic pain treatment in our centre.

Keywords: Radiofrequency, Sacroiliac joint, Impar ganglia, Heel, Sciatic nerve, Visual analogue scale (JPMA 61:879; 2011).

Introduction

The pulsed radiofrequency (PRF) developed as an alternative to the continuous radiofrequency thermocoagulation (CRFT) applications has been widely used in medicine in recent years. It is applied easily, is effective without causing thermal damage to the tissue and is a painless operation which has been widely used. PRF, which can be applied in a similar way to the CRFT applications, (for example, facet medial nerve or trigeminal nerve applications) is different from CRFT mainly with the peripheral applications. It was stated that PRF was applied successfully in the treatment of disorders such as myofascial trigger points,¹ phantom limb pain,² occipital neuralgia,³ meralgia paresthetica,⁴ chronic testicular pain,⁵ secondary glossopharyngeal neuralgia,⁶ suprascapular nerve applications for the treatment of chronic shoulder pain,⁷ postherpetic neuralgia⁸ and premature ejaculation.⁹

With the help of an electrode placed next to the nerve tissue with CRFT applications, it is provided to damage the nerve fibers which carry the pain signal thermally.¹⁰ This damage results in coagulative necrosis, which is not different from other neurolytic procedures in terms of concepts used to damage the sensorial pathways in the target tissues for chronic pain treatment.¹¹ On the other hand, in PRF applications, RF energy is applied at a high voltage (typically as 45 V), with bursts of 20 millisecond pulses of 500 kHz and with the subsequent silent phase of 480 milliseconds.¹ As a result, the tissue heat composed due to the long silent phase spreads around and does not exceed 42°C. Therefore, since the tissue temperature will stay under 45-50°C, accepted as the "irreversible tissue damage threshold," permanent tissue damage and neuritis-like reactions do not occur.^{12,13} Although it is applied very frequently, the PRF effect mechanism has not been completely understood.⁵ However, it is considered that PRF has rather a neuromodulator effect.¹⁴

Based on results of the pioneering studies published, we have been applying PRF for treatment of chronic pain developing due to various aetiologies in our pain management centre for the last few years. The aim of this retrospective pilot study was to assess the efficacy of PRF on different anatomical regions in patients suffering from chronic pain of various aetiologies, and to share its good results with others.

Patients and Methods

For this retrospective cross-sectional study conducted at the Pain Management Centre, Dicle University, Diyarbakir, Turkey, the PRF applications applied to 24 patients with different types of chronic pain were compiled by scanning the patients' files retrospectively. The data was collected between October 2008 and September 2010. Approval for the study

was obtained from the Institutional Review Board of the university. All the applications were done in the pain treatment centre of a university hospital using the outpatient method. The patients were symptomatic despite previously applied various conventional treatments. They were offered PRF implementation for the treatment of their chronic pain as an alternative therapy. After all the patients were informed both verbally and in writing about the applications, their written consent was taken stating that they accept the application. The PRF applications consisted of "sacroiliac intra articular PRF for sacroiliac origin pain," "heel PRF for heel pain," "sciatic nerve PRF for the sciatic damage that develops after inadvertent injection" and "impar ganglion PRF for coccygodynia."

The following patients' selection criteria were used for the PRF applications;

1- For all the applications; a) presence of a chronic pain lasting for a minimum of 3 months, b) failure to obtain adequate response to previous conservative treatments including medical treatment and physical therapy,

2- For sacroiliac PRF applications; a) predominantly axial pain below the L5 vertebrae, b) greater than 75% pain relief from two separate intra-articular blocks with no more than 2 ml of injectate per block, c) short lasting pain relief (less than one month) from therapeutic sacroiliac joint injection with 40 mg triamcinolone acetonide in 1% bupivacaine,

3- For impar ganglion PRF applications; a) pain being limited in the coccygeal area, b) greater than 75% pain relief from diagnostic impar ganglion block with 2 ml of 1% lidocaine, c) short lasting pain relief (less than one month) from therapeutic impar ganglion block with 40 mg triamcinolone acetonide in 1% bupivacaine,

4- For heel PRF applications; a) greater than 75% pain relief from diagnostic heel injections with 2 ml of 1% lidocaine, b) short lasting pain relief (less than one month) from trigger point injections with 40 mg triamcinolone acetonide in 1% bupivacaine,

5- For sciatic nerve PRF applications; a) greater than 75% pain relief from sciatic nerve block with 5 ml of 1% lidocaine using nerve stimulator, b) short lasting pain relief (less than one month) from therapeutic sciatic nerve block with 40 mg triamcinolone acetonide in 1% bupivacaine.

The following criteria were used for exclusion from the PRF applications;

1- A known history of allergies to substances that are to be used (e.g. local anaesthetics, opaque substance), Haemorrhagic diathesis and systemic infection or local infection where the procedure was to be applied.

All the applications were performed under local

anaesthetic and sedoanalgesia when required. Prior to the application, vascular access was done on the patients and they were given 0.9% isotonic sodium chloride solution via intravenous infusion. The operations were applied with the guidance of routine monitorization (3 lead ECC, TA and pulse oximetry). For all the PRF applications, Baylis Radiofrequency generator and cannula-probe sets (Baylis Medical Inc., Montreal, Canada) were used.

Procedures:

Sacroiliac intra articular PRF applications:

All interventions were performed with C-arm fluoroscopy. The patients who were prepared as explained above were positioned on the fluoroscopy table in prone position. After the operation region was cleaned with iodine-based antiseptic solution, it was draped according to sterility rules. After taking to C-arm Anterior-posterior (AP) position, the sacroiliac joint where the operation would be conducted was viewed. The lower one-third section of the sacroiliac joint was determined as the access point. After the skin-subcutaneous tissue was infiltrated with lidocaine of 1%, 100 mm long 22 gauge RF introducer with 10 mm active tip was placed intraarticularly. After the stylet in the introducer was taken out and 0.5-1 ml opaque substance was injected, the intra articular placement was confirmed. Following that, the RF probe was passed through the introducer and PRF was applied with 42°C temperature and a pulse width of 20 millisecond at 2 Hz for 15 minutes. After the application was completed, the patients were transferred to the recovery room where they were supposed to stay for 2 hours. They were followed by the experienced clinic nurse in the recovery room against early complications. The patients were discharged from the hospital by suggesting that they come for a control 1 month later, in accordance with our routine practical applications.

Impar ganglion PRF applications:

Patients who were to receive PRF due to coccygodynia were taken onto the fluoroscopy table in prone position after being prepared as described above. Unlike the others, since the region where the operation was to be applied is prone to infection, a single dose antibiotics (cefazolin 1 gram) was applied intravenously as prophylactic. After the operation region was cleaned carefully with iodine-based antiseptic solution, it was draped in accordance with sterility rules and as the access region left open. In order to view the sacrococcygeal region, C-arm was taken to lateral position. All the operations were applied via transdiscal method. As the access point, sacrococcygeal or between 1st and 2nd coccygeal disc space were determined. After the skin-subcutaneous tissue was infiltrated with lidocaine of 1%, a 50

mm long 22 gauge cannula with 2 mm active tip was passed through the disc spaces perpendicularly. As soon as the needle tip was taken out from the anterior face of the disc space, 0.5 ml of opaque substance was injected to provide the typical opaque spread in the target region. By taking the flouroscope to AP position, the spread of the opaque substance in the medium line was also controlled. Later, the RF probe was passed through the cannula and PRF was applied with 42°C temperature, pulse width of 20 millisecond and for 15 minutes. The patients who were kept in the recovery room for 2 hours after the application were discharged with suggestions.

Heel PRF:

The patients prepared as explained above were taken onto the fluoroscopy table in supine position. The foot on which the application was to be done was laid in external lateral decubitus position and with C-arm fluoroscopy, the bottom section of the calcaneal bone was determined. After the skin-subcutaneous tissue was anaesthetized with lidocaine of 1%, 50 mm long 22 gauge cannula with 5 mm active tip was placed into the sole of the foot and the cannula was moved forward parallel to the vertical axis of the body until the calcaneus bone was touched. After that, the application was done with the same PRF setting. The patients who were kept in for 30 minutes after the operation were discharged by suggesting that they rest for 1 day to prevent the pain from starting again.

Sciatic nerve PRF:

This group of operations were using the blind technique without the C-arm fluoroscopy. The patients, who were prepared for the operation as explained above, were laid on their side on the examination table according to the classical labat technique in such a position as the leg to be operated would be on the upper side. After the access region was cleaned and covered according to sterility rules, the skin-subcutaneous tissue was anaesthetised with 1% lidocaine. The 22 gauge with 10 mm active tip 100 mm long RF cannula was moved forward perpendicularly from the marked point. By giving sensory stimulation at 50 Hz, a feeling of pain or paresthesia was created in legs and feet with voltage between 0.3-0.5 V. On the other hand, by giving motor stimulation at 2 Hz, movement in legs was provided at the voltage between 0.4-0.8 V. After positive stimulation, three cycles of PRF for 120 s at 40 V were performed. The temperature was held constant at 42°C. The electrical parameters used were a frequency of 2 Hz and a pulse width of 20 milliseconds.⁷ After the access point was covered with a plaster following the application, patients were taken to the recovery room where they stayed for 2 hours. Later, the patients were discharged and told to come back in 1 month for check up.

Outcome measurements:

The pain of the patients was evaluated by 10 cm Visual Analogue Scale (VAS). In this scale, "0" identifies the situation where no pain exists and "10" identifies the most severe pain that can be imagined. The VAS scores in the initial and the last follow-ups were collected for analysis.

In addition, the ages of the patients, gender, duration of symptom, the side of the application, and follow-up duration were also collected from the patients' files. In addition to this, if there were any complications that occurred during the application or in the follow-up periods, were also noted for analysis. The values are given as mean±Standard Deviation (SD).

Statistical analysis:

All data were analyzed using the statistical package SPSS version 11.0 for Windows (SPSS Inc, Chicago, IL, USA). Kolmogorov-Smirnov test was used to determine whether the data had a normal. Wilcoxon signed ranks test was used to perform pairwise comparisons. Also, we used the Spearman correlation coefficients to study the effects of various factors on the outcomes. $P < 0.05$ was considered statistically significant in all analyses.

Results

A total of 24 patients were applied pulsed RF for various reasons. Of these 15 (62.5%) were females. Table-1 shows the different sites of PRF application. The mean age of all the patients was 41.3±16.9 (range 15-77) years. The mean follow-up time was 0.5±5.4 (range 2-20) months. While the overall VAS score of all the patients was 6.5±1.0, it was found as 3.0±1.5 in the last follow-up attendance ($P < 0.000$) (Table-2).

Sacroiliac intraarticular PRF applications:

On nine patients, sacroiliac intraarticular PRF application was performed. The mean age of this group of patients was 43.6±17.0 (range 21-70) years and five were male. Bilateral application was done in five patients and unilateral in four patients. The mean pain duration was estimated as 30.9±34.7 months. The mean VAS score of the

Table-1: Patients Characteristics.

No	Age (year)	Gender symptom	Duration of application (month)	Type of	Side
1	21	F	12	SACROILIAC PRF	Bilateral
2	55	F	30	SACROILIAC PRF	Bilateral
3	70	M	36	SACROILIAC PRF	Bilateral
4	24	M	24	SACROILIAC PRF	Right
5	38	F	120	SACROILIAC PRF	Right
6	63	F	12	SACROILIAC PRF	Bilateral
7	38	M	24	SACROILIAC PRF	Left
8	33	M	11	SACROILIAC PRF	Bilateral
9	50	M	9	SACROILIAC PRF	Right
10	57	F	24	IMPAR PRF	N/A
11	33	F	18	IMPAR PRF	N/A
12	20	F	18	IMPAR PRF	N/A
13	46	F	13	IMPAR PRF	N/A
14	60	M	32	IMPAR PRF	N/A
15	39	F	84	IMPAR PRF	N/A
16	35	F	42	IMPAR PRF	N/A
17	25	M	50	IMPAR PRF	N/A
18	62	F	3	HEEL PRF	Bilateral
19	33	F	48	HEEL PRF	Right
20	29	F	108	HEEL PRF	Right
21	15	M	12	HEEL PRF	Left
22	33	F	24	SCIATIC PRF	Left
23	77	F	11	SCIATIC PRF	Left
24	35	M	6	SCIATIC PRF	Left

F, Female M: Male
N/A, Not Applicable.

patients was 6.7±0.9 prior to the application, which reduced to 3.1±1.5 in the last follow-up ($P = 0.007$). The mean follow-up duration was 10.2±3.4 (range 7-17) months (Table-2).

Impar ganglion PRF application:

In this group, there were eight patients, of whom six were female. The mean age was 39.4±14.3 years and the mean pain duration was 35.1±23.5 months. The mean Baseline VAS score mean was 6.4±1.1, which decreased to 3.1±1.8 in the last follow-up ($P < 0.026$). The mean follow-up period was 8.9±6.4 (range 2-20) months (Table-2).

Heel PRF applications:

A total of four patients received PRF. While one of

Table-2: Table showing the changes in the VAS values of patients and the follow-up times.

	No. of patients	VAS baseline mean±SD	VAS The last mean±SD	P	Patient portion showing 50% decrease in the VAS score	Follow-up time mean±SD (month)
Total	24	6.5±1.0	3.0±1.5	.000*	66.7	8.5±5.4
Sacroiliac PRF	9	6.7±0.9	3.1±1.5	.007*	55.6	10.2±3.4
Impar PRF	8	6.4±1.1	3.1±1.8	.026*	75.0	8.9±6.4
Heel PRF	4	6.0±0.8	2.3±1.3		75.0	7.5±7.9
Sciatic nerve PRF	3	7.3±1.2	3.7±1.5		66.7	3.3±0.6

VAS, Visual Analog Scale; SD, Standart Deviation.

*Statistically significant difference

Note: Since the number of patients in heel PRF and sciatic PRF applications were a few, statistic was not performed.

Table-3: Effects of various factors on outcome.

			The mean change in the VAS score
Spearman's rho	Duration of pain	Correlation Coefficient	-0.454(*)
		Sig. (2-tailed)	0.026
		N	24
Age		Correlation Coefficient	-0.114
		Sig. (2-tailed)	0.596
		N	24

* Correlation is significant at the 0.05 level (2-tailed).
VAS, Visual Analog Scale.

these patients received PRF for a chronic pain developed due to trauma, the other three patients received PRF for heel spur. The mean age of the patients was 34.8±19.7 years and the mean symptom duration was 42.8±47.6 months. The mean baseline VAS score was 6.0±0.8, which declined in to 2.3±1.3. The mean follow-up time was 7.5±7.9 (range 2-19) months (Table-2).

Sciatic nerve PRF applications:

Three patients received PRF in this group. The mean age was 48.3±24.8 years and the mean symptom duration was 13.7±9.3 months. All three patients received PRF on the left side. The VAS scores of the patients decreased from 7.3±1.2 to 3.7±1.5 at the end of mean 3.3±0.6 (range 3-4) months of follow-up (Table-2).

Moreover, based on the results from the final follow-up, we studied the effects of various factors such as age and duration of symptom on outcome. While a negative correlation was observed with the duration of symptoms, no correlation was found with the age (Table-3).

Safety:

No early- or late-term complications that may develop due to the application, such as bleeding, haematoma, infection or nerve damage were observed in any of the PRF applications.

Discussion

The presented study showed, a minimum 50% decrease in the VAS scores in 16 of 24 patients who received PRF for various reasons compared to the initial scores. While the percentage of the patients in the sacroiliac PRF group whose VAS scores showed ≥ 50% decrease was 55.6, this value was found as 75.0, 75.0 and 66.7 in the impar, heel and sciatic nerve PRF groups respectively.

Radiofrequency heat treatments have been used successfully in the field of medicine for over 30 years for various pain syndromes.¹⁰ However, the fact that the conventional RF applications are painful in general, the risk of neuritis and deafferentation pain and the possibility of

damaging the other nerve fibres unintentionally have been the main disadvantages of this application. On the other hand, the fact that the conventional RF applications applied at low temperature are as effective as the RF applied at high temperature, lead to the research for different RF modes.¹⁵

In an article published by Sluijter et al. in 1998 it was shown that heat was not the only responsible factor for pain relief.¹⁶ In an experimental study on rats, after 3 hours following the pulsed RF application to dorsal root ganglion, it was stated that in the superficial laminae of the dorsal horn, there was a significant increase in the number of the cFOS-immunoreactive neurons. Considering this, it was found that the PRF current activated the neurons operating the pain in the dorsal horn independent from the heat lesion.¹⁷ In addition, an electromagnetic field is created during the PRF's active phase. This electromagnetic field is considered to cause a cellular change that leads to a decrease in transmission of pain impulses, independent of the heat lesion.¹³

All this information enables the isothermal procedures to become widespread and eliminated the undesired potential neurological complications that may develop in the adjacent nerves due to the heat in the conventional RF applications.¹⁸ Thus, Cahana et al.¹⁰ confirmed in one of their reviews that, when compared with continuous RF, PRF has a neuro-selective property which aims at small-diameter nerves such as A σ and C fibres and that it is a more reversible and a less destructive application. However, the authors emphasized that it was not known how PRF procedures modified the central and peripheral pain pathways and that in vitro and in vivo studies had to be done to determine this.

Sluijter et al. suggested that intraarticular PRF application may have a dual effect. According to this theory, the primary effect is to explain the decrease in the pain immediately observed in small joint applications. When intra-articular PRF is applied to small joints, it is suggested that the electric current given is to remain in the joint space and that there is a strong current even in distances far from the electrode (normally the current power decreases as getting away from the electrode). According to this theory, the fact that pain relief is seen soon after the application is considered to be related to the PRF effect mainly on the nervous system. However, since the electrode is not directly placed in a position next to the nerve in this application, the response to sensorial stimulation will be negative; also, the patients do not state sensations during application. However, it is assumed that it would cause the minimal stimulation of the nociceptive nerve endings and sooner or later might cause the long-term depression of the primary synapse. The second effect of intraarticular application is

particularly seen in larger and geometrically open joints (knee, shoulder, etc). When PRF is applied to larger joints, the fact that pain relief does not occur immediately, but gradually, makes us consider that the electric field has an effect mainly on immune cells (which will effect the production of anti-inflammatory cytokines). Among the immune cells, since there is the intensive crosstalk to which cytokines intervene, the electric field on a limited region around the electrode tip possibly provokes a more generalized response.¹⁹

As far as we know, there is only one case report about impar PRF application in the literature. In this case report where a patient with benign origin, coccygodynia was applied impar PRF application for 4 minutes. The authors reported that the NRS score which was 8 at the beginning decreased to 0 as soon as the application was done and that the score was around 1-2 in the control in the 4th month.²⁰ On the other hand, in our study where we applied impar PRF to 8 patients with chronic coccygodynia, 75% of our patients described minimum 50% decrease in their pain scores and provided an idea on the efficiency of this method.

A literature review showed, that sciatic nerve pulsed RF applications had been done only on animals as experimental models.^{11,13} In our study, we presented our PRF applications on 3 patients suffering from neuropathic pain due to sciatic nerve injury. Two of the patients reported minimum 50% decrease in their pain scores, while the other patient stated that his pain score decreased to 5 from 8. To confirm this better result, long term follow-up period prospective, EMG controlled studies are required.

We applied calcaneal PRF to a total of four patients, three of whom had chronic heel pain due to heel spur and one of whom had chronic heel pain that developed as secondary to trauma. We have not found any studies in the English literature regarding this application with which we achieved success in 75% patients. However, as far as we know, there are four similar but technically different studies in the literature related to this subject.²¹⁻²³ In these studies, contrary to our study, conventional RF was applied to the medial calcaneal nerve for pain relief.

The sacroiliac origin pain believed to be the cause of 15-10% of chronic low back pain is probably among the most complicated and mysterious causes of low back pain.²⁴ To treat such type of pains which are usually difficult to diagnose is also difficult. PRF applications is one of the methods that can be applied for the treatment of sacroiliac origin pain which does not respond to conventional methods such as medical treatment, physical treatment and intra articular steroid injection. However, the number of studies

regarding this subject are very few. In a case series carried out by Sluijter et al., a case was applied sacroiliac PRF as intra-articular.¹⁹ In another study,²⁵ which was carried out prospectively, PRF was applied to dorsal rami nerves that innerve sacroiliac joint rather than intraarticular application, which is different from our method. At one week after the application, it was stated that 16 (72.7%) patients showed minimum 50% or more pain relief. However, it was stated that this pain-free period had lasted for 17-32 weeks only on 7 (31.8%) patients As for our study, 55.6 % of our patients showed $\geq 50\%$ pain relief after a mean of 10.2 ± 3.4 months follow-up time. At first, these results make us think that intraarticular PRF application is more long-lasting. Yet, in order to verify this assumption, it is required to carry out wide series prospective studies that compare both methods.

Generally, PRF application is an expensive treatment modality because the price of a set of RF canulla and needle is about \$1500 in our country. However, when considering the whole treatment cost of patients suffering from chronic pain, this method may not be very expensive. Hence, PRF application may consider being a cost-effective treatment modality.

The main limitation and weakness of our study is that it is a retrospective, time bound study. In addition, the fact that our study was carried out on a limited number of patients, is another important handicap. However, we believe that our study made an important contribution in terms of providing an opinion regarding the applications which have very few examples, such as impar ganglion and sacroiliac intra articular PRF applications or applications whose examples have never been seen, such as sciatic nerve and heel PRF applications. However, the results obtained with this study must be confirmed with a sufficiently wide sample volume and prospective randomized controlled studies.

As a result, in this study carried out with the pulsed RF that is developed as an alternative to conventional RF which is a neurodestructive method, a considerable number of successful results have been achieved in patients who have chronic pain complaint originating from different anatomic regions. This study, in which none of the patients experienced major or minor complications, revealed that PRF is also an effective and safe method in such different types of applications.

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