CLINICAL REPORT

Pulsed Radiofrequency of Pudendal Nerve for Treatment in Patients with Pudendal Neuralgia. A Case Series with Long-Term Follow-Up

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■ **Abstract:** Pudendal neuralgia (PN) is an impairing neuropathic disorder, affecting both men and women, involving a severe burning and sharp pain along the course of the pudendal nerve. Treatment is often insufficient, and options are limited. Pulsed radiofrequency (PRF) is a technique which might be useful in therapy. This case series aims to determine the effectiveness of PRF in patients with PN in the context of evaluation of care. Between 2010 and 2016, all female patients of University Medical Center Utrecht diagnosed with PN who experience insufficient pain relief after common treatment were offered PRF. Patient Global Impression of Improvement (PGI-I) scores were assessed at 3-month follow-up and at long-term follow-up (median 4 years). PGI-I scores were recorded to evaluate our quality of care. Twenty patients with PN consented to undergo PRF. We lost one patient in follow-up. Seventy-nine percent of the patients described their condition as "(very) much better" at 3-month follow-up. At long-term follow-up, 89% of the patients described their condition as "(very) much better." No serious side effects were observed. In conclusion, PRF is a successful treatment option in patients not responding to standard treatment options, including pudendal nerve blocks. PRF of the pudendal nerve can be used for PN to provide relief in patients' chronic pelvic pain. ■

Key Words: pelvic pain, pudendal neuralgia, pulsed radiofrequency

INTRODUCTION

Chronic pelvic pain (CPP) is a common condition, presenting a major challenge in health care, due to its complexity of etiological factors, great number of possibly involved structures and insufficient response to therapy. In 4% of the patients, the pudendal nerve is responsible for the development of CPP.[1]

Pudendal neuralgia (PN) is an impairing neuropathic disorder, affecting both men and women, involving a severe burning and sharp pain along the course of the pudendal nerve. It is often provoked by sitting, and relieved by standing or laying down.[2,3] Because PN can be both unilateral and bilateral, and various branches of the nerve might be involved, clinical presentation is diverse.[1] Neuropathy of the pudendal nerve leads to pathological changes of its motor and sensory functions. Furthermore, pelvic floor muscle overactivity is often present.[4] PN is mainly induced by pudendal nerve entrapment at the level of the piriformis muscle, between the gluteus maximus

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fascia and the sacrospinous ligament, between the sacrospinous ligament and the superior gemellus fascia, or within the pudendal canal, called Alcock's canal.[5,6] Most common etiologies of PN are mechanical injury by prolonged compression from excessive sitting, or repeated injury from bicycle rides, trauma (eg, during childbirth), and iatrogenic damage during surgical procedures.[1,4]

Several therapies have been described for PN. If there is an obvious cause, like sutures constricting the pudendal nerve, the therapy should be immediate removal of the suture. However, the cause of PN is not always easy to determine. Therefore, treatment is often focused on pain reduction, with the aim on recovery of function and quality of life. The first and most important option in therapy is a change of lifestyle (reducing painful activities, like cycling and sitting on pads) to reduce further injury to the nerve. In addition, pelvic physiotherapy can reduce pelvic floor muscle overactivity. First-line treatment is pharmacological, including acetaminophen, nonsteroidal anti-inflammatory drug (NSAIDs), anti-epileptic drugs, and antidepressants. Most patients have slight to moderate improvement in pain with noninvasive treatment modalities.[2] If these treatment modalities do not provide an acceptable pain relief, invasive treatment modalities can be considered, such as pudendal blocks and surgical decompression. Pudendal blocks are used in both diagnostic process and long-term pain relief.[2,6,7] In a retrospective descriptive study of Benson and Griffis, only 31% of the cases improved after pudendal nerve blocks and 60% improved after surgical decompression.[2]

Because no treatment is effective for all patients, other treatment options are investigated. Pulsed radiofrequency (PRF) is a successful treatment modality in patients with several neuropathic pain syndromes, such as cervical radicular pain and occipital neuralgia.[8] Based on observations in clinical practice, it was hypothesized that PRF could have a place in therapy of PN. Fang et al.[9] described improvement in patients with PN treated with PRF in combination with pudendal block until 3 months. Hence, the present case series aims to determine the long-term effectiveness of PRF in patients with PN who have no long-term pain relief after pudendal blocks with local anesthetics.

METHODS

Setting and Participants

All female patients at the University Medical Center Utrecht, diagnosed with PN between 2010 and 2016 who experienced no or little improvement after standard treatment, consisting of noninvasive treatment modalities and pudendal blocks with local anesthetics, or who had bilateral PN were offered PRF. PN was diagnosed according to all essential "Nantes Criteria."[10] Patients experienced pain in the territory of the pudendal nerve, predominantly while sitting, and the pain does not awake patients during sleep at night. During physical examination, no objective sensory impairments were found. Other signs that confirm the diagnosis are allodynia, numbness, or tenderness in response to pressure in the distribution of the pudendal nerve. Finally, diagnosis PN was confirmed by diagnostic pudendal nerve block with 10 ml lidocaine 1%.[4,10]

Standard treatment consisted of change of lifestyle, pelvic floor physiotherapy, and oral medication for neuropathic pain (eg, amitriptyline and pregabalin). In case of no improvement, pudendal blocks with 10 ml levobupivacaine and 40 mg methylprednisolone were introduced. The injections were given transvaginally into the interligamentous space. In case of no long-term improvement or if the patients developed bilateral PN, PRF was proposed. Patients were asked to fill out the Patient Global Impression of Severity (PGI-S) score before introduction of PRF to rate the severity of their pain. The PGI-S score expresses the severity of patients' symptoms, rating from 1 (normal) to 4 (severe).[11]

Pulsed Radiofrequency

One gynecologist (author K.J.S.) performed PRF from 2010 until January 2018. From January 2018, PRF is carried out by anesthesiologists at the Pain Clinic, using the same technique. Patients were positioned in lithotomy position. The ischial spine and attachment of the sacrospinous ligament were identified transvaginally after disinfection with povidone-iodine. At 1.5 cm medial to the ischial spine, a 22-gauge 5 mm active tip RF needle was advanced approximately 2 cm close up to the pudendal nerve. The impedance was recorded and should be between 100 and 500 Ω. Thereafter, sensory stimulation at 50 Hz was performed, the sensory threshold should be below 0.5 V. If necessary, the needle was repositioned. When acceptable stimulation was obtained, a 45 V radiofrequency current was delivered in pulses of 20 ms with a frequency of 2 Hz. Treatment duration was 240 seconds. In case of bilateral pain, the procedure was performed on both sides. In case of positive response (ie, pain relief) to the PRF

treatment, the treatment was repeated when pain recurred.

Data Collection

We evaluated quality of care by the subjective improvement of symptom severity, measured by the Patient Global Impression of Improvement (PGI-I) score 3 months after the first PRF and after long-term follow-up, at least 2 years. The PGI-I score describes how much benefit a patient notices after PRF, rating from 1 (very much better) to 7 (very much worse).[11] Successful treatment is defined as "(very) much better" on the PGI-I scale (score 1 or 2).

Data Analysis

Statistical analysis was performed using SPSS statistics version 25. Summarized patient characteristics were age, parity, inducement of PN, duration of pain before PRF, and PGI-S. Means with standard deviation, medians with ranges, and percentages of categorical variables were calculated. A graphical reproduction was made to visualize the change in PGI-I scores over time. Informed consent was obtained from all patients to collect data for evaluation of care.

RESULTS

Between 2010 and 2016, 20 patients were diagnosed with PN and consented to undergo PRF. Table 1 shows patients' characteristics at the start of PRF. The duration of pain relief after PRF varied from 6 weeks to 6 months. We repeated the treatment when pain recurred.

Table 1. Baseline Characteristics

Age, years	50.6 (12.5)
Parity, *n*	2 (0 to 2)
Duration of pain before PRF, months	29 (5 to 226)
Localization of pain, *n*	
Bilateral	18 (90%)
Unilateral	2 (10%)
Presumed cause of PN, *n*	
Idiopathic PN	7 (35%)
Vaginal delivery	5 (25%)
Vaginal surgery	5 (25%)
Cystitis	3 (15%)
PGI-S score, *n*	
Severe (4)	14 (70%)
Moderate (3)	4 (20%)
Mild (2)	2 (10%)
Normal (1)	0 (0%)

Variables are shown as mean with standard deviation (age), median with range (parity, duration of pain), and numbers with percentage (localization of pain, inducement of PN, and PGI-S).
Abbreviations: PGI-S, patient global impression of severity; PN, pudendal neuralgia; PRF, pulsed radiofrequency.

In 20 patients, a total of 430 treatments were done. Two patients only received one PRF treatment. Of the remaining 18 patients, the number of procedures per patient varied from 2 to 71.

Figure 1 shows PGI-I scores of 19 patients 3 months after their first PRF and at long-term follow-up. We lost one patient in follow-up. Seventy-nine percent of the patients assessed their condition 3 months after PRF compared to their condition before PRF as "(very) much better" (score 1 or 2). Only one patient (5.3%) assessed her condition after PRF as "much worse" (score 6).

We re-examined PGI-I scores of the 19 patients after long-term follow-up. Repeated PRF therapy was performed in 18 patients, with a median interval duration of 3 months (range = 6 weeks to 6 months) between 2 sessions. The patient who assessed her condition as "much worse," at 3 months follow-up did not get repeated PRF. At 3.5 years follow-up, she still assessed her condition as "a little worse" after other treatment modalities. Of 18 patients, the follow-up period varied from 2.3 to 8.8 years, with a median follow-up of 4 years. All patients whose condition was "(very) much better" at 3 months follow-up still assessed their condition as "(very) much better" at long-term follow-up. Three patients assessed their condition as "a little better" at 3 months follow-up. After repeated PRF, the condition of two of these patients was assessed "(very) much better." One patient assessed her condition as "no change," so PRF was no longer performed. These results correspond to a success rate of 89% at long-term follow-up.

Major complications did not occur in this group with more than 400 PRF treatments. The only mentioned side effect is short-term vaginal bleeding. No infections occurred after any of the procedures. No neurological side effects were observed, especially no fecal or urinary incontinence.

DISCUSSION

Pulsed radiofrequency (PRF) is a successful treatment for PN in patients not responding to both noninvasive treatment options and pudendal blocks. Seventy-nine percent of the patients assessed their condition as "(very) much better" at 3 months follow-up. Repeated PRF therapy was executed in most patients because of the positive effects every 2 to 6 months. Patients' condition at long-term follow-up was (very) much better in 89% of the patients. Because the long-term results did not

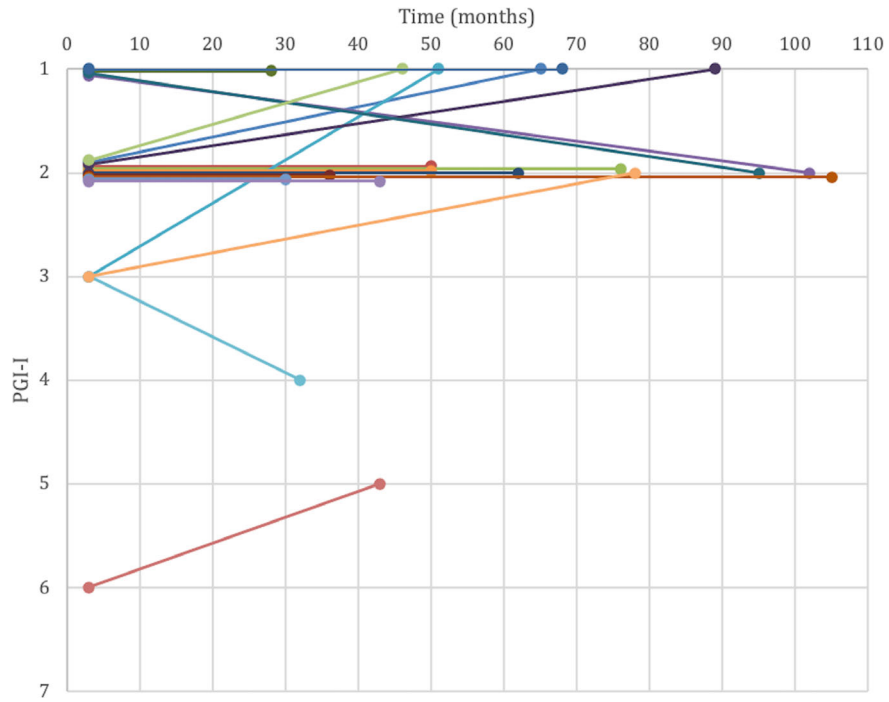

Figure 1. All patients suffering from pudendal neuralgia and treated with pulsed radiofrequency, arranged by Patient Global Impression of Improvement (PGI-I) scores 3 months after first pulsed radiofrequency and after long-term follow-up (*y*-axis). Length of follow-up is shown in months on the *x*-axis. PGI-I score: 1 = very much better; 2 = much better; 3 = a little better; 4 = no change; 5 = a little worse; 6 = much worse; and 7 = very much worse.

change after switch of practitioner, we conclude effectiveness of PRF is doctor-independent and reproducible.

The high success rate of 89% after repeated PRF with long-term follow-up is comparable to the success rate (92.1%) described by Fang et al. in a randomized controlled trial with only 3 months follow-up. They described 77 patients with PN, divided into 2 groups of 38 patients receiving PRF with pudendal nerve block (NB) and 39 patients as the control group, receiving only NB with local anesthetics. PRF as well as the NB were performed under the guidance of ultrasound. Clinical effective rate was 92.1% in the PRF group, and only 35.9% in the NB group at 3 months follow-up.[9]

Compared with other treatment options, both pudendal NBs with local anesthetics and surgical decompression are less effective than PRF, with success rates of 31% to 35.9% for pudendal NBs[2,9] and 60% for surgical decompression.[2]

In line with the study of Fang et al.,[9] the complication rate in PRF for PN is low. No severe side effects were observed in the PRF group, nor in the NB group. Although we did not use ultrasound or any other form of imaging to perform PRF of the pudendal nerve, we did not encounter any major complications as well. Only little vaginal blood loss is seen directly after PRF.

The mechanism of action of PRF is not well known. Unlike continuous radiofrequency, which delivers continuous current, PRF delivers high intensity current in pulses, allowing heat to eliminate during the latent period so the tissue temperatures will not raise above 42°C.[12,13] A study of Hamann et al. shows that PRF selectively targets neurons whose axons are small in diameter, specifically A-delta and C nociceptive fibers. This is in line with the absence of sensory and motor loss following PRF.[14] Hence, along with a long-term follow-up, repeated PRF shows no complications or motor loss, and thus can be repeated if pain recurs. An additional advantage of PRF compared with other invasive treatment options for PN, like pudendal NB, is that no computed tomography scan or ultrasound is required to perform the procedure.[6] Correct needle placement can be confirmed with sensory stimulation.

This case series is not primarily designed as a study. We have used the PGI-S and PGI-I to evaluate our own quality of care. Therefore, a limitation of this case series is the low internal validity, due to the lack of a placebo

control group. Although including a placebo control group in our population is possible, we question if it is ethically justified to perform a randomized controlled trial (RCT) in this population. A study of Van Zundert et al.[15] showed that conducting sham-controlled RCTs in interventional pain management has important ethical and methodological limitations. Another limitation due to our quality of care measures is the fact pain relief is assessed by a single question PGI-I score. This leaves place for various biases. More extensive evaluation of pain relief should be included in a larger study to assess the effectiveness of PRF in more detail.

We performed PRF in a group of patients not responding to either noninvasive treatment options and pudendal blocks. Within this group of patients, PRF seems a responsible choice. Further research and larger series are necessary to investigate if the effect of the PRF could be extended, for example, by adding medication. Furthermore, because the success rate of PRF is high and the complication rate is low, it is interesting to question the place of PRF as a primary therapy for all patients with PN.

CONCLUSION

In this case series, the effectiveness of repeated PRF in patients with PN after a median 4 years follow-up is 89%. These patients assess their condition as (very) much better. It shows PRF is an effective, minimally invasive treatment with little side effects of PN in patients who did not respond to standard treatment. However, treatment should be repeated after 2 to 6 months. It is valuable to consider PRF as first-line treatment in patients with a proven PN.

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CONFLICT OF INTERESTS

All authors have no conflicts of interest to declare.

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