Efficacy of pulsed radiofrequency treatment on the saphenous nerve in patients with chronic knee pain

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Abstract. Background and objective: We studied the long-term efficacy of pulsed radiofrequency treatment (PRF) on the saphenous nerve in 115 patients with chronic knee pain.

Materials and methods: 115 patients with chronic knee pain were investigated in a period of 22 months retrospectively. All patients had pulsed radiofrequency to the saphenous nerve. The mean age was 59 (range, 51–67). All patients were access ed with the visual analog scale (VAS) and WOMAC score pain at rest, pain on movement, and pain in flexion at 10th day, 3rd and 6th months post procedure.

Results: All patients showed improvement in their VAS scores as well as in their WOMAC scores after ten day, three month, and 6 months (p = 0.001). No side effects were reported.

Conclusion: PRF application to the saphenous nerve for eight minutes showed remarkable amount of patient satisfaction. Application of PRF for the second time could be recommended if it shows some benefit after the sixth month. But none of our patients needed a second application of PRF after six months period.

Keywords: Pulsed radiofrequency, saphenous nerve, knee pain, pain relief, peripheral nerve, osteoarthritis

1. Introduction

Knee osteoarthritis (OA) is the most frequent and common cause of lower extremity pain and disability in the general population [1]. The intra-articular injection of steroids is a popular practice, but the duration of action of such injections is limited and there may be deleterious effects if they repeated so often. Unfortunately, pain medicines could have undesirable side effects: many NSAIDs, such as aspirin, may cause gastrointestinal distress, and narcotic painkillers carry a risk of addiction [2,3]. The benefits of exercise can be compromised by skeletal or muscle damage or in-

jury, and injections give only temporary relief of pain. Therefore, it is necessary to explore additional treatments [4] for OA of the knee to better manage pain, save pain medication, and restore the knee function.

Pulsed radiofrequency (PRF) is a minimally neurodestructive technique in pain management caused by disorders effecting the peripheral nerves. It involves the placement of a radiofrequency (RF) electrode in proximity to the neural target structure and delivery of an RF signal output from an RF generator to that structure. The difference is that in continuous radiofrequency (CRF), the signal output is typically a continuous wave of RF voltage, whereas in PRF, the RF wave is broken up into short bursts of signal output between which are time periods of no signal at all. The PRF causes neuromodulation by effecting sodium channel activity changes in c-fos production in medulla spinalis [5,6]. In the typical CRF technique, the tissue
is heated grossly by electrical energy dissipation, and it is the tissue heating that leads to localized destruction of the neural tissue and consequent interruption of neural signaling. This has historically been called the RF heat lesion. The typical PRF technique is characterized by much lower average temperature elevations of the target tissue because of the smaller duty cycle on time of the PRF pulsatary RF output. Indeed, PRF is often effective without raising the average target tissue temperature above 42°C, which has been traditionally been thought to be below the irreversible tissue destruction threshold of 45°C to 50°C [7]. However, there are limited studies examining the effects of pulsed electrical stimulation in humans.

Saphenous nerve is identified as a peripheral nerve for the treatment of patients with chronic knee pain. The PRF is a safe method at the heat levels below 42°C, and any neurologic complications have been reported in the current literature [8]. These saphenous nerve PRF treatments are based on the relationship of the nerves to the superior pole of the patella. The purpose of this trial was to assess the outcome in terms of patient satisfaction, functional recovery, fatigue and psychological variables during the six months of PRF treatment applied to the saphenous nerve and the requirement of the application of PRF.

2. Material and methods

After obtained informed consents, 115 OA patients were enrolled to the study. 68 female and 47 male with chronic knee pain were investigated retrospectively in a period of 6 months. The protocol of this clinical trial was approved by the hospital ethical committee and the written informed consent of the patients were obtained. Procedures were performed in Kartal Koşuyolu and GATA Haydarpaşa Hospital, Department of Anesthesiology Division of Algology between the dates 01.12.2006–01.12.2008.

Patients were aged greater than 59 years and had knee pain persisting more than 6 months. All patients continued to get their medications for pain control during the trial as they were before. They were required to have a well-established diagnosis of OA of the knee. Radiographs were required as part of the diagnosis of OA. The diagnoses were made by pain care physicians. Patient follow-ups were done for six months.

2.1. Inclusion criteria

All patients had received several conservative therapies for knee pain, patients with functional class I–III, radiographically confirmed OA of the knee (bilateral femorotibial compartment narrowing and sharpening of the tibial spines), including oral analgesics, intraarticular steroid or local anesthetic injections and physical therapy.

2.2. Exclusion criteria

Psychiatric conditions, and adverse effects to the local anesthetics, coagulation disturbances, malignancy, use of pacemaker, insulin pump, any implanted electrical device; active phase of inflammatory joint disease and other systemic inflammatory diseases, gout; pseudogout; avascular necrosis and osteonecrosis.

All patients were accessed with a 100 mm visual analogue scale (VAS) as pain at rest, pain on movement, pain in flexion at preprocedure, the tenth day, the third month, and the sixth months postprocedure period and patients’ satisfaction was evaluated by the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) [9] score preprocedure and, tenth day, third and 6 months after the procedure (Fig. 1). All outcome measures were evaluated at baseline and at 10th day, and 3rd month, and 6th months. Standard patient and laboratory findings and safety assessments were depicted at baseline.

Patients, admitted to pain clinic were received oral analgesics (NSAIDs), performed intraarticlar steroid or local anesthetic injections and physical therapy. So, PRF was decided to use as an alternative treatment method in the patients who did not have any benefits from the other treatment options. All patients performed pulsed radiofrequency to the saphenous nerve and a second application of PRF was not offered to the patients before six months. PRF was applied with 20-millisecond bursts at a frequency of 2 per second (2 Hz) for 120 seconds times, total of 8 minutes (Neurotherm JK4A radiofrequency generator). Use of other drugs and side effects were recorded. Underlying etiology of the presenting clinical symptoms of knee pain was documented by the radiologic findings and were defined as with the followings: 1. Previous knee operation, 2. Chronic trauma, 3. Gonartroses.

All procedures were performed with the patient in supine position and the leg is extended at the knee, and the long axis of the foot was at a 90° angle to the table under fluoroscopic guidance. The main landmark for the entrance is the tibial tuberosity, an easily recognizable and felt bony prominence on the anterior aspect of the tibia a few cm distal to the patella and the infrapatellar branch of the saphenous nerve was agreed with...
pressure spot. PRF application was carried out using sterile technique. Skin infiltration was performed with 1 cc of lidocaine 1%. RF stimulator jet (thermocouple electrode) needle; a SMK 5 or 10 needle with an active tip of 5 mm and its position was verified with electrosimulation at 50 Hz and or at 2 Hz stimulation. The needle position was corrected if below 0.5 V a sensory (50 Hz) or motor (2 Hz) response was obtained. The needle tip should be perpendicular to the nerve utilizing ideal effect of the electrical region. The PRF treatment was consisted of passage of RF current of 2 Hz at 40 volts with 20 msec active and 480 msec silent periods. It was maintained for 120 seconds for 4 times whereby the temperature was below 42°C.

Patients were assessed preprocedure and the tenth day, then the third, and the sixth months after the procedure for pain relief by a 100 mm VAS. On this scale, patients were asked to show their pain on the scale as no pain to worst possible pain (no pain, mild pain, moderate pain, severe pain and worst pain imaginable). Function was assessed by use of the WOMAC criteria (global, pain and disability score).

Results were analyzed by use of the one-way ANOVA tests (Figs 1, 2). Frequencies of knee pain during follow-up duration provides valuable information for evaluation of patient satisfaction. Baseline demographic statistics were calculated overall and by treatment group for age, sex, duration of arthritis, and location of OA. Mean, Standard deviation, minimum, maximum were calculated for continuous variables, and counts and percentages were calculated for categorical variables.

3. Results

There were a total of 115 patients had knee pain as their primary complaint. The demographic data, descriptive statistics, overall and by treatment group, were shown in Table 1.

The mean age of the sample subjects was 59 years (range, 51–67) with respect to OA disease history of the knee. Male to female ratio was 47/68. All patients were taking NSAIDs before the procedure. There were no significant differences between treatment groups with respect to these baseline characteristics. The duration of symptoms were 45 ± 6.4 months. The length of follow-up was 6 months. Analysis of the follow-up observations on each patient showed significant improvements in the WOMAC global score ($p = 0.001$), WOMAC pain score ($p = 0.001$), WOMAC disability score ($p = 0.029$) at compared to baseline in the sixth month. Beneficial effects of the procedure was observed on the tenth day in 115 (100%) patients and reported pain relief with decreased in VAS scores >83% and continued until the end of the trial in 94 (81.73%) patients. 97 patients (84.33%) showed improvement in their VAS scores as well as in their WOMAC scores after 6 months ($p = 0.001$). The response of patients to pulsed radiofrequency after 10 day, 3 months, and 6 months were all given in percentage and patient satisfaction was evaluated by > 50% decrease in VAS and
The response of patients to pulsed radiofrequency (PRF) after 10th day, 3rd month, and 6th month are all given in percentage. Patient satisfaction is evaluated by > 50% decrease in VAS and by WOMAC scores which are collected 6 months after treatment.

<table>
<thead>
<tr>
<th>Patient response to different treatment</th>
<th>Number of patients (%)</th>
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<tbody>
<tr>
<td>Patient requiring second dose of PRF treatment after 3 months</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Patient requiring second dose of PRF treatment after 6 months</td>
<td>3 (2.6%)</td>
</tr>
<tr>
<td>Patient reporting &gt; 50% decrease in VAS after 6 months</td>
<td>115 (100%)</td>
</tr>
<tr>
<td>Patient reporting satisfaction by WOMAC Score after 6 months (excellent or good)</td>
<td>113 (98.2%)</td>
</tr>
</tbody>
</table>

There was a statistically significant reduction in the VAS and WOMAC scores and in pain and disability of the WOMAC index at patients after the pulsed radiofrequency to the saphenous nerve (Fig. 1, 2). All data were expressed as means (Table 3). Tukey was used as Post Hoc test.

Several investigators have shown the usefulness of the obturator nerve block and the femoral nerve block as a diagnostic and therapeutic tool for patients with hip joint pain [11,12]. Malik et al. and Kawaguchi et al. demonstrated percutaneous, continuous radiofrequency lesioning and percutaneous sensory nerve electrocoagulation of sensory articular branches of the hip joint for long term relief of hip joint pain [13,14]. In a study of Wu, PRF has been applied to obturator and femoral nerves that had resistant hip pain. Patients have 50% pain relief for three or four month’s period [15]. Also, in a study of Malik et al., performed PRF to ob-

Table 3

<table>
<thead>
<tr>
<th>Main of WOMAC index</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC Global</td>
<td>5.06</td>
<td>2.81</td>
<td>(0.94, 9.18)</td>
</tr>
<tr>
<td>WOMAC Pain</td>
<td>0.88</td>
<td>0.68</td>
<td>(0.06, 1.82)</td>
</tr>
<tr>
<td>WOMAC Stiffness</td>
<td>0.32</td>
<td>0.48</td>
<td>(−0.29, 0.94)</td>
</tr>
<tr>
<td>WOMAC Disability</td>
<td>3.62</td>
<td>2.30</td>
<td>(0.64, 6.69)</td>
</tr>
</tbody>
</table>

Expressed as mean ± SD.

Fig. 2. VAS at resting, in motion and in flexion. There is significant correlation between the VAS scores before and after the treatment at 1st, 3rd and 6th months period (one-way Anova) (p < 0.001).

4. Discussion

The saphenous nerve is the largest cutaneous branch of the femoral nerve and the only cutaneous branch to originate from the posterior division. It arises in the femoral triangle, descends lateral to the artery and then enters the adductor canal of Hunter, where it crosses in front of the artery to lie on its medial side. The nerve escapes from the lower part of the canal by emerging between sartorius and gracilis, runs down the medial border of the tibia immediately behind the great saphenous vein, crosses with the vein in front of the medial malleolus and reaches as far as the base of the great toe, supplying an extensive cutaneous area over the medial side of the knee, leg, ankle and foot. Immediately on leaving the adductor canal, the saphenous nerve gives off its infrapatellar branch, which pierces sartorius and is distributed to the skin immediately below the knee as part of the patellar plexus [10].

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It is not yet clear how PRF exactly works, and how exposure to an electric field can relieve pain. However, PRF may cause subliminal stimulation of nociceptive nerve endings, eventually causing long-term depression of the first synapse [18]. Sluijter suggested that PRF could be used as an alternative treatment method in patients who did not respond to the other treatment options [19]. PRF is recently being performed successfully as a non-destructive method [8]. The second effect could possibly reflect an action of electric fields on immune cells, thus influencing the production of anti-inflammatory cytokines. Although osteoarthritis is considered to be a non-inflammatory condition, increased levels of proinflammatory cytokines such as interleukin (IL)-1b, tumor necrosis factor a and IL-6 have been described, probably regulating the progression of the process [20]. An Italian study by Protasoni et al. [21] indicates that transmission electron microscopy reflected changes in T gangliar cells, enlarged cisternae, and numerous vacuoles. Myelin coverage was not adherent. This was confirmed by Tun et al. [22], where it was stated that “PRF treatment may cause separation in myelinated axons. These changes all seem to be reversible. PRF may have a selectively greater effect on the smaller pain-carrying fibers and a lesser affect on the larger A-beta neurons that mediate non-pain-related sensation. So, the mechanism of action of PRF remains unclear”.

In the study of Rozen PRF was performed to T12, L1, L2 nerve roots and they observed 75% to 100% pain relief. sensory stimulation was performed at 50 Hz to ascertain paresthesias in the dermatome only and not in the lower extremity. Motor stimulation was then tested at 2 Hz to elicit contraction in the paraspinal muscles for T12 and inguinal and upper thigh only for L1, L2 nerve roots and no lower extremity fasciculation was noticed at up to 2 V stimulation. Procedure was tolerated well and no complications were observed [23].

In an other study Sluijter performed PRF to C3–C6 mediastral branches. PRF of 45 V was applied for 10 minutes, with a pulse width of 10 ms. At 4-week follow-up, there was complete relief of pain. In an other patient the needle with a 15 mm active tip was placed into the knee joint space and PRF was applied for 10 minutes, with a pulse width of 10 ms and 60 V. At 4-week follow-up, there was complete relief of pain [24]. In the manuscript of Rohof [17] they performed PRF to suprascapular nerve. The PRF treatment consists of passage of RF current of 2 Hz at 40 volts with 20 msec active and 480 msec silent periods. The treatment is maintained for 2 minutes. We performed similar practice as described in the studies above. In our study; the PRF treatment on the saphenous nerve was consisted of passage of RF current of 2 Hz at 40 volts with 20 msec active and 480 msec silent periods. It was maintained for 120 seconds for 4 times.

Shah and Racz performed PRF to suprascapular nerve who had chronic shoulder pain. Patients had 4–5 months of pain relief and improvement in shoulder function, without deterioration in muscle strength [25]. Also in our patients we observed pain relief and functional improvements for six months period. Alcidi et al. [26] reported considerable amelioration in pain due to knee osteoarthritis by application of low power radiofrequency therapy. Yamagami et al. [27] investigated the effects of RF in 69 patients who had knee osteoarthritis. They applied RF 90 seconds at 70–80°C. It was effective in 75.4% of patients, and the serious complication was not recognized. VAS of 69 cases was significantly improved from 52.5 ± 9.8 to 22.4 ± 13.9. In our patients beneficial effects were observed on the tenth day in 100% patients with decreased in VAS scores >83%. Thermocoagulation was not effective in all of their cases, but PRF was effective in all of our patients with the improvements at VAS values and without any serious complication.

These studies lead us to perform PRF on saphenous nerve which gives the sensorial innervation of the knee. All patients suffer from knee OA and they did not respond the medical and other conservative therapies. In our study 84.33% of the patients showed improvement in their VAS scores as well as in their WOMAC scores after 6 months and also PRF was performed on saphenous nerve without any complication. But this study

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has obvious limitations: First, like the follow up interval for pain improvement was short. Second, there was no placebo group because of the hospital policy. So, the results of this study therefore reflect the patient satisfaction, functional recovery, fatigue and psychological variables during the six months period and thus may not be generalized.

In conclusion, this clinical trial showed a statistically significant benefit in terms of reduction VAS and WOMAC in patients with chronic knee pain resistant to conventional care. These results suggest that pulsed radiofrequency treatment of the saphenous nerve was beneficial in reducing pain and disability in patients with chronic knee pain. But, it certainly must be confirmed with new randomized control trials using different types of PRF treatment protocols at saphenous nerve in different patient populations.

References


