Pulse dose radiofrequency on knee osteoarthritis

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Authors: S. Masala¹, R. Fiori², A. Chiaravalloti¹, E. Calabria¹, M. Raguso¹, M. Morini¹, G. Simonetti¹; ¹Rome/IT, ²Cecchina/IT  
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Aims and objectives

Knee osteoarthritis (OA) is a leading cause of disability in older adults [1]. OA has a growing prevalence in people [50 years of age [2]. Important risk factors are aging and obesity [1]. Mechanical stress has also a pivotal role. OA early appears in joints underload as knee one [2]. Symptoms related by patients with knee OA include pain, stiffness, joint instability, functional limitations, and muscle weakness [2]. Conservative approaches include physical therapy, analgesics drugs, intra-articular injection of steroids, and visco-supplementation [3]. Sometimes these therapies are not successful, and, in a small percentage of patients, adverse effects can occur [4, 5]. Good results are not always achieved with surgery. Main surgical approaches are arthroscopy and total knee joint replacement [6, 7]. Currently joint replacement is associated with increased morbidity [7]. In the 1970s, radiofrequency (RF) was used for the treatment of chronic pain unresponsive to conservative therapies [8]. An RF needle with an "active tip" is positioned near the target nerves and, like an electrode, it transfers an alternative electrical current (in the frequency of radio waves) created by an RF generator [8]. The electrical current can be transferred in a continuous or pulsed manner. In continuous radiofrequency (CRF) applications, tissue temperature reaches 60-80 C with lysis of the target nerves [8-10]. CRF was successfully performed the first time for the treatment of trigeminal neuralgia [11], and then it was applied for the following types of: medial branch neurotomy and sacroiliac joint CRF in low back pain [12, 13], CRF for treatment of chronic pain due to cervical facet arthropathy [14], RF for treatment of malignant pain [15], and discogenic pain [16]. Pulsed radiofrequency (PRF) was introduced in 1998 as a nonlytic alternative to CRF [17]. The tissue temperature does not exceed 42 C, and no irreversible tissue damage occurs [18-20]. PRF has been performed in the abovementioned CRF applications, in peripheral joints, and in other neuropathic syndromes [19-25]. An RF generator produces pulses with amplitude of 45 V and duration of 20 ms; a silent phase of 480 ms follows each pulse [26]. In this way, when pulses radiate the tissues, the local temperature reaches the ideal value of 42 C; however, may exceed this number. Therefore, the RF generator modifies parameters of the subsequent pulses until the temperature falls within the limit of 42 C: the signal amplitude (volt) or the pulse duration are often modified [26]. Pulse-dose radiofrequency (PDRF) is a technical evolution of PRF. In PDRF, the number of pulses are established according to the joint treated. In PDRF, pulse parameters include amplitude of 45 V and an "active phase" with 20-ms duration followed by a 480-ms silent phase. If the tissue temperature exceeds 42 C, the RF systems stop the next pulses until the temperature decreases to this value. The purpose of this study was to investigate the effectiveness and the safety of PDRF for the management of chronic pain in patients with knee OA.
Methods and materials

The study was approved by our Institutional Review Board, and informed consent was obtained from all patients. They were informed about the technique, the benefits, and the potential complications of the procedure as well as postprocedure care. Between January 2011 and November 2012, PDRF was performed on 40 patients (22 male; 18 female) with a median age of 65.3 years (range 59.2-74.5) and a diagnosis of knee OA. The diagnosis of knee OA was documented with x-ray examination (Opera, Swing, General Medical Merate, Italy). We excluded patients with associated pain causes, such as radicular pain, intermittent claudication (diabetic or nondiabetic vasculopathy), or neurological disorders. All pain causes were documented with ultrasonographic (vasculopathy), electromyographic (neurological disorders, radicular pain), or spine magnetic resonance imaging (radicular pain) studies. We enrolled only patients with an advanced OA, which is defined as 3rd- or 4th-degree OA according to the Kellgren-Lawrence classification below [27]. All patients refused surgery. 1. Grade 3: moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour; 2. Grade 4: large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour. Pain relief was not achieved with conservative therapies during the last 6 months. Patients had not received benefits from physical therapy, analgesic drugs (nonsteroidodal anti-inflammatory, opioid), intra-articular injection of steroids, or visco-supplementation. The average duration of symptoms was 20 months. Pain intensity was recorded on a 10-cm visual analogue scale (VAS) ranging from zero (no pain) to 10 (maximum pain ever had) [28]. Exclusion criteria were coagulation disorders, systemic or local infection in the interested area, psychiatric disorders, or excessive use of opioids. Forty-four joints were treated with PDRF. Four patients received bilateral treatment in the same session. All procedures were performed in an intervention room. The patient was placed in a supine position on the fluoroscopy table, and vital signs were monitored by a nurse. The treated knee joint was flexed to 15. No genicular block tests were performed. Under fluoroscopic guidance (Allura, Philips, The Netherlands) the antero-posterior projection of the tibiofemoral joint was obtained to make the femoral and tibial bone outlines as aligned as possible. In this way, a real representation of the joint space was achieved. The anterolateral region of the interested knee was disinfected with an iodine-based antiseptic solution, and the area was anesthetized with 1 % lidocaine. A 20-gauge cannula, 10 cm in length, was introduced and placed in an equidistant point from the femoral and tibial bone borders. With lateral fluoroscopic projection, the cannula was positioned in the center of the joint space (Fig. 1). After the spindle was removed, an RF needle, with a 10 mm "active tip," was introduced (Fig. 2). The RF needle was positioned in the joint space to treat pericapsular nerves endings, which were responsible for painful symptomatology. Therefore, no stimulation was needed after the needle was in position. The following parameters were used to perform PDRF (Neurotherm, Neurotherm Inc., Wilmington, Massachusetts): 1,200 pulses at high voltage (45 V), with 20-ms duration followed by 480-ms silent phases. After the end of the procedure, the patient was monitored for...
30 min by a nurse; then, he or she returned home with the suggestion of rest for the following days. Patients could use ice and take paracetamol if they had pain in the treated region. Finally they could mobilize the next day as comfort allowed. All patients underwent an adequate physiotherapy program after treatment. For each patient, follow-up was performed with clinical examination at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. Each time VAS scores were recorded. Improvement in quality of life (QOL) was evaluated using the Western Ontario and McMaster Universities (WOMAC) Index of Osteoarthritis [29]. A series of 24 questions, which investigated pain, stiffness, and physical function, was used to provide information about the patient's autonomy in daily life. The overall score was between 0 (no disability) and 96 (lack of autonomy). Patients answered the WOMAC questionnaire before the procedure and during each follow-up after treatment. Paired-samples Student t test was used to compare mean VAS and mean WOMAC scores with baseline values at each follow-up. A p-value < 0.05 was considered statistically significant in all analyses. The values were given as mean +/- SD.
Images for this section:

**Fig. 1:** A 20-gauge RF cannula with 10-cm length placed in the antero-lateral region of interest in the treated knee under fluoroscopic guidance. A Positioning of the cannula. B AP fluoroscopic projection. C Lateral fluoroscopic projection

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**Fig. 2:** An RF curved needle with a 10-mm active tip placed under fluoroscopic guidance. A Positioning of the needle. B AP fluoroscopic projection. C Lateral fluoroscopic projection

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Results

Technical success, defined as the correct positioning of the device in the absence of complications, was achieved in all cases. PDRF decreased patient pain and improved autonomy. Processing of data obtained before and after the procedure revealed mean VAS scores (Graphic 3). Means WOMAC scores documented an improvement in QOL (Graphic 4). All of the observed differences were statistically significant (p<0.05). VAS and WOMAC scores dramatically decreased 1 week after treatment (mean VAS scores 1.8 ± 0.4; mean WOMAC scores 18 ± 1.6). In the following months, there was stabilization of painful symptomatology (means VAS scores 1.9 ± 0.2 at 1 month, 2.0 ± 0.5 at 3 months, and 2.1 ± 0.3 at 6 months after PDRF). Patients also had improved autonomy in daily life (mean WOMAC scores 21 ± 0.6 at 1 month, 20 ± 1.4 at 3 months, and 23 ± 1.9 at 6 months after PDRF). There was a slight increase of mean VAS and WOMAC scores at 1 year after PDRF, although they never reached the initial values (mean VAS scores 2.3 ± 0.6; mean WOMAC scores 30 ± 1.7). Finally, no patients developed complications (infection, hemorrhage, thermal injury, loss of motor and sensory control in the corresponding area of the genicular nerves) during the early or late period of follow-up. This study successfully investigated the effectiveness and the safety of PDRF in patients with chronic pain unresponsive to conservative therapies. Many studies have shown the clinical effectiveness of PRF, which is defined as a decrease of painful symptomatology [20, 24, 25, 30]. In the study by Karaman et al. [20], PRF was performed with an intra-articular approach in 31 patients. Investigators had good results in the mid-term. Sluijter et al. [24] successfully performed PRF in different joints (cervical facet, shoulder, knee, sacroiliac, atlanto-axial, and radiocarpal joints) in 6 patients with OA. Ozyuvaci et al. [30] documented in 3 patients with gleno-humeral OA the role of PRF for palliative management of chronic pain. Finally, Halim et al. [25] achieved good results with intra-articular PRF for the treatment of the atlanto-axial arthropathy. Some studies have investigated the biological effects of PRF [17, 31-33]. PRF did not cause irreversible tissues damage [31]. In an acute phase of OA, histological studies showed only impairment of the architecture of myelin sheath bundles along the axons. There was also interstitial edema, which persists for weeks after the procedure [32]. Erdine et al. showed ultra-structural changes that especially involved the nociceptive fibers (C- and A-delta fibers) [33]. There is no evidence for long-lasting structural effects of PRF [17]. Other studies have suggested a modulatory effect caused by an alteration in pain signaling [34]. Sluijter et al. [24] affirmed a dual effect in the intra-articular application of PRF. Radio waves influence the nervous system by suppressing the excitatory C-fiber response and, finally, the synaptic transmission. This could explain the immediate pain relief, particularly observed in small-joint application. The second effect is an influence on the immune response (which instead explains the progressive improvement in large-joints applications, such as knee and shoulder). Radio waves affect immune cells and stop production of proinflammatory cytokines, such as interleukin-1b and interleukin-6. Therefore, the investigators affirmed that PRF affects intercell communication by way of these cytokines by causing a more generalized response. PDRF is a technical
evolution of PRF. In PRF, technique pulses parameters change if the tissue temperature exceeds 42 C. When PDRF is performed, the RF generator can provisionally stop the pulses; however, their number and their parameters are always constant. Therefore, PRF’s clinical effectiveness (pain relief) and its biological effects should be expected in PDRF application. We documented in the mild period of OA the clinical effectiveness of PDRF, which is defined as a decrease of painful symptomatology. We also verified improved patient autonomy in daily life. The safety of the PDRF, defined as absence of complications, was also shown. We preferred the intra-articular approach. Our targets were in fact pericapsular nerve endings, which have only sensorial function. Our purpose was to alter transmission of the pain signal. Our hypothesis is supported by the previously mentioned histological studies of PRF technique [24, 34]. Furthermore, no stimulation was needed after the RF needle was positioned in the joint space, and no diagnostic genicular block tests were necessary. In fact, motor fibers cannot be damaged because of PDRF’s neuromodulatory effects. This study had some limitations. There are no data that investigate the long-time effectiveness of PDRF. It is necessary to perform a prospective, double-blind, randomized clinical trial, which may confirm the results shown in our study.
Fig. 3: Mean VAS scores before PDRF and at 1 month, 3 months, 6 months, and 1 year after the procedure. The graphic shows the decrease of painful symptomatology in patients treated with percutaneous PDRF of knee OA (p<0.05)

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Fig. 4: Mean WOMAC scores before PDRF and at 1 month, 3 months, 6 months, and 1 year after the procedure. The graphic shows the improvement of QOL in patients treated with percutaneous PDRF of knee OA (p<0.05) S. Masala et al.: PDRF for Knee Osteoarthritis 123 Author's personal copy

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Conclusion

In conclusion, PDRF is a promising technique for the palliative management of chronic pain unresponsive to conservative treatments.
References