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Ultrasound-Guided Percutaneous Neuromodulation in Patients with Unilateral Anterior Knee Pain: A Randomized Clinical Trial

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Abstract: The objective of this study was to evaluate the short-term and crossover effects of a percutaneous neuromodulation (PNM) intervention on the femoral nerve, regarding the pain, knee flexion motion (range of motion (ROM)), and functionality, in patients with unilateral anterior knee pain (AKP). Our study used a randomized clinical trial design. Thirty patients were divided into two groups: one asymptomatic knee group in which patients received stimulation in the femoral nerve corresponding to the nonsymptomatic knee; and one symptomatic knee group, in which patients received stimulation in the femoral nerve corresponding to the painful knee. Pain, knee flexion ROM, Victorian Institute of Sport Assessment-Patella (VISA-P) and Kujala questionnaires were evaluated. Twenty-eight patients completed the study. Compared to their baseline values, both groups showed an increase immediately at 24 h, and at 1 week for the knee flexion ROM variable. In addition, the symptomatic knee group showed an increase for the Kujala score and a decrease for the numeric rating scale (NRS) variable from baseline to 1 week. VISA-P score did not show statistically significant differences for the time-group interaction. After the intervention, there were no differences between the groups in any measured time. Conclusion: a single-shot ultrasound-guided PNM intervention per week in the femoral nerve may be an effective treatment for improving the pain, knee flexion ROM, and knee functionality. In addition, this technique produces crossover benefits in the nonintervention limb.

Keywords: anterior knee pain; femoral nerve; percutaneous electrical nerve stimulation; chronic pain; ultrasound; physical therapy; neuromodulation

1. Introduction

Anterior knee pain (AKP) is characterized by a nonspecific pain around the patella. AKP is one of the most common problems of the knee, mainly affecting active people [1].

The underlying cause of AKP has been suggested to be multifactorial [2,3], such as patella abnormalities, muscle disbalance, or malalignment of the lower extremities [4,5]. However, some researchers have suggested that AKP may be caused by slight nerve damage or altered mechanosensitivity of the femoral nerve, like other musculoskeletal pathologies [6,7]. Rodríguez-Fernández et al. [6] found a decreased excitability in the common fibular nerve in patients with functional instability of the ankle and De-la-Cruz-Torres et al. [7] identified a decreased excitability of the radial nerve in patients with chronic unilateral epicondylalgia. In relation to the knee, Sanchís-Alfonso et al. [8] suggested a “neural model” to understand AKP. They found that a hyperinnervation in the lateral retinaculum, mainly nociceptive substance P-positive nerves, is involved in the pathogenesis of AKP. Lin et al. [9]

found an alteration in the mechanosensitivity of the femoral nerve, measured by a slump test, in patients with AKP. Therefore, the authors suggest that AKP may be the result of sensitization of the neural system and not only a local mechanical problem.

Determining an effective intervention that helps to treat the neural condition is very important. To the best of the authors' knowledge, there is limited evidence in regard to "neural therapy" in patients with AKP. The electrical stimulation of the peripheral nervous system is a therapeutic procedure that applies the electric current on the peripheral nerve to treat pain. The underlying mechanism of this therapeutic effect is caused by the stimulation producing a modification of the input to the central nervous system, known as neuromodulation. Since its first description by Wall and Sweet in 1967 [10], the peripheral nerve stimulation (PNS) efficacy for chronic neuropathic pain limbs has increased significantly. Ilfeld et al. [11,12] demonstrated that percutaneous femoral nerve stimulation may be effective in providing analgesia following anterior cruciate ligament reconstruction or total knee arthroplasty.

Clinically, an invasive technique has appeared, known as ultrasound (US)-guided percutaneous neuromodulation (PNM). [13] This minimally invasive intervention consists of the application of a percutaneous electrical stimulation (PES) through an acupuncture needlelike electrode that is placed in close proximity to the nerve or motor point of the muscle with ultrasound guidance. [13] In this way, García-Bermejo et al. [14] observed that a single PNM intervention on the femoral nerve may cause a decrease in pain and increase the ROM in patients with AKP, which was greater at 24 h after the stimulation. Álvarez-Plats et al. [15] demonstrated that US-guided PNM on the femoral nerve may reestablish the quadriceps strength in inhibited muscles in subjects with knee pathology.

Different studies provide evidence of the crossover effect, understood as the response of a nonexercised contralateral limb. There is extensive conflicting evidence in the literature. Several authors have showed that unilateral stretching [16,17] and foam rolling [17] may have a crossover effect on the contralateral limb ROM; others [18,19] suggested that there were crossover fatigue effects in the contralateral knee extensors; and Regueme et al. [20] did not support the existence of crossover effects after exhaustive stretch-shortening cycle exercise. Regarding the crossover effect after neural intervention, De-la-Cruz-Torres et al. [21] showed that PNM in the sciatic nerve produced benefits in the hip flexion ROM, measured by a straight leg raise test, in the nonintervention limb.

The purpose of this study was to evaluate the short-term effects of the US-guided percutaneous femoral nerve stimulation, regarding the pain, knee flexion ROM, and functionality in patients with unilateral AKP. In addition, another aim was also to compare the crossover effects of PNM intervention delivered to the contralateral limb.

2. Materials and Methods

2.1. Participants

We recruited a sample of 30 (16 females, 14 males) active participants with unilateral AKP. The patients showed different types of lesion, such as chondropathy, meniscopathy, or arthroscopy of the internal meniscus. They were divided randomly (using a coin) into two groups: patients in the asymptomatic knee group ($n = 15$) received stimulation in the femoral nerve corresponding to the nonsymptomatic knee, while patients in the symptomatic knee group ($n = 15$) received stimulation in the femoral nerve corresponding to the painful knee. As described in detail previously [14], subjects who had the presence of pain in the anterior knee (≥ 3 months) were included. The exclusion criteria were: taking pain medication; being under any treatment; belonephobia; history of lumbar pathology; history of fracture in any part of the body; history of neurological or orthopedic disorders; diagnosis of herniated disk; bilateral symptoms; electrophysiological findings referable to other peripheral nerve; and body mass index (BMI) < 20 or > 30 kg/m².

The local ethics committee approved the study, which complied with all the principles set forth in the Declaration of Helsinki. All subjects signed informed written consent forms to participate in this

study. This trial was registered in the clinical trials data-base (clinicaltrials.gov), with registry number NCT03883737. Individuals were recruited from the private clinic. The recruitment period was from 14 April to 1 November, 2019. Figure 1 provides a flowchart of subject recruitment during the study.

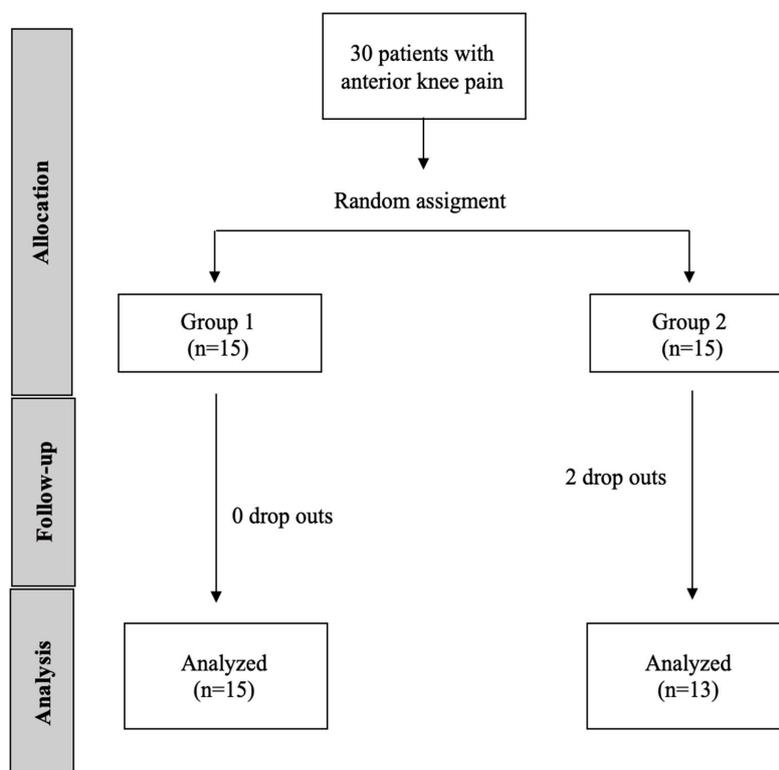


Figure 1. CONSORT flow diagram of patient recruitment and retention.

2.2. Clinical Assessment

Demographic data were obtained including age, weight, height, body mass index (BMI), gender, symptom duration, and pathological side. Severity of average pain in the anterior knee was evaluated using the numeric rating scale (NRS) (0, no pain; 10, worst pain). Knee flexion ROM was measured by universal goniometer [22]. To measure the angle of knee flexion, the patient was placed in a supine position with the knee and hip of the symptomatic limb flexed at 90° , with the contralateral leg extended. The knee was then passively flexed by the examiner until the participant reported the onset of pain in the anterior region of the knee. The examiner was blinded after the assignment of interventions. The axis of the universal goniometer remained on the lateral epicondyle of the femur, with the movable arm on the midline of the lateral face of the fibula and with the fixed arm on the midline of the lateral face of the thigh, aligned with the greater trochanter [23]. The intraclass correlation coefficient (ICC) was used to determine the reliability of the measurements and it was established based on the 10 volunteered patients as sufficient for clinical measurement (ICC = 0.95). Pain and functional ability over the previous week were evaluated using the Victorian Institute of Sport Assessment-Patella (VISA-P) scale [24,25] and the Kujala questionnaire [17,26]. VISA-P is the only condition-specific scale for patellar tendinopathy. This self-administered questionnaire consists of 8 items: 6 are used to evaluate pain levels or disability in daily activities and specific functional tests and 2 provide information regarding ability to play sport (asymptomatic patient, 100 points; disability, maximum 0 points) [15,24]. The Kujala questionnaire is a specific, time-saving, and easily understandable tool for patellofemoral pain (asymptomatic patient, 100 points; disability, maximum 0 points) [26,27].

All variables were measured at baseline, immediately after, after 24 h, and after 1 week following the intervention.

2.3. Ultrasound-Guided Percutaneous Neuromodulation Intervention

All patients received a single PNM intervention, that is, a PES procedure. Specifically, this consisted of the application of a square wave biphasic electrical current, with 10 Hz frequency, a 250 μ s pulse width, and the tolerable intensity to cause a visible muscle contraction for a total of 1.5 min, following the procedure described by Valera and Minaya [13]. A specific device, Physio Invasiva[®] (PRIM, Madrid, Spain), was used. The subjects were lying in a supine position and the femoral nerve was located over the femoral triangle using an ultrasound machine (General Electric, Logiq e, Wisconsin, USA) with a 12 L linear probe, in a transverse section. The underlying skin was cleaned with isopropyl alcohol. Subsequently, a stainless steel acupuncture needle (0.30 mm \times 30 mm) (Agu-punt, Barcelona, Spain) was inserted with a short axis approach, with an 80° tilt from the skin surface, until the perineurium of the femoral nerve was reached (Figure 2). A physiotherapist with 7 years of experience in invasive therapy administered the PES intervention.

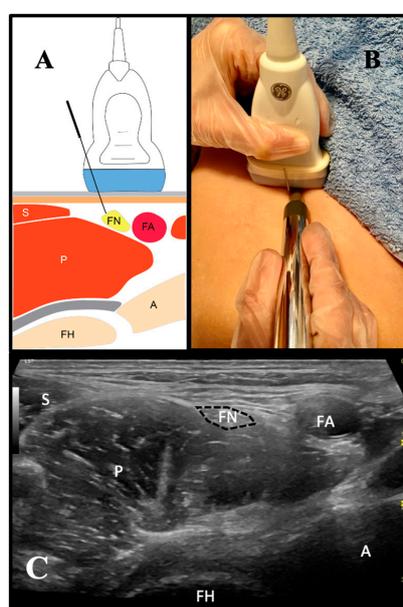


Figure 2. Ultrasound-guided percutaneous neuromodulation (PNM). (A) Percutaneous electrical stimulation (PES) intervention in the femoral nerve; (B) ultrasound-guided invasive approach of the femoral nerve; (C) ultrasound image of the intervention. Abbreviations: A, acetabulum; FA, femoral artery; FH, femoral head; FN, femoral nerve; S, sartorius muscle; P, psoas muscle.

2.4. Sample Size Calculation

A convenience sample based on the De-la-Cruz-Torres et al. [28] novel research about percutaneous stimulation in the flexor hallucis muscle was carried out. For this study, a total sample of 30 subjects were recruited (15 patients for each group) at the private clinic.

2.5. Data Analysis

SPSS statistics version 23.0 software (IBM SPSS Statistics; NY: IBM) was employed for data analysis. The Shapiro–Wilk test was used for the normality assumption. The Student’s *t*-test was used considering the homogeneity of variance using the Levene’s test for the baseline comparison. In order to assess the effects of intrasubject (time) and intersubject (intervention) values on the dependent variables, a two-way analysis of variance (ANOVA) for repeated measures was developed. Moreover, the Bonferroni’s correction post-hoc analyses were carried out. The level of significance was set at $p < 0.05$ than α error of 0.05 (95% confidence interval) and a desired power of 80% (β error of 0.2).

3. Results

In total, 28 patients participated in the study. Considering Table 1, there were no significant baseline differences between both groups in any of sociodemographic data and clinical measurements. Most of the painful knees were the patient's right knee (87%) because there were 26 subjects with dominance on the right side and four subjects with dominance on the left side.

Table 1. Sociodemographic data and baseline values of clinical variables for each group.

Data	Asymptomatic Knee Group (n = 15)	Symptomatic Knee Group (n = 15)	p-Value
Age (years)	37.0 ± 9.6	39.3 ± 9.5	0.52
Weight (kg)	71.7 ± 8.9	65.6 ± 9.5	0.09
Height (m)	1.68 ± 0.09	1.65 ± 0.06	0.30
BMI (kg/m ²)	25.5 ± 3.5	24.0 ± 2.7	0.26
Injury time (months)	7.0 ± 2.6	7.2 ± 2.7	0.82
Gender (F/M)	11/4	10/5	N/A
Dominance side (R/L)	14/1	12/3	N/A
Pathological side (R/L)	13/2	12/3	N/A
ROM (o)	129.0 ± 11.70	133.5 ± 6.4	0.228
NRS	56.4 ± 14.56	56.9 ± 18.88	0.939
Kujala	78.8 ± 10.60	73.2 ± 6.70	0.116
VISA-P score	59.0 ± 12.90	50.2 ± 18.90	0.102

Abbreviations: BMI, body mass index; F, female; Kg, kilograms; L, left; M, male; m, meter; NRS, numeric rating score; R, right.

Regarding Table 2, intrasubject (time) statistically significant differences with a large effect size were shown for knee flexion ROM [F(3,78) = 47.998; $p = 0.001$; Eta2 = 0.649], NSR [F(3,78) = 11.562; $p = 0.001$; Eta2 = 0.308], Kujala [F(3,78) = 6.835; $p = 0.001$; Eta2 = 0.208] and VISA-P [F(3,78) = 4.054; $p = 0.01$; Eta2 = 0.135] variables. In addition, the Bonferroni's correction post-hoc analyses showed statistically significant differences from baseline to 1 week for the Kujala score, knee flexion ROM, and NRS variables. VISA-P score did not show statistically significant differences for the time-group interaction. Finally, there were no intergroup statistically significant differences.

Table 2. Numeric rating score (NRS), range of motion (ROM), Kujala, and Victorian Institute of Sport Assessment-Patella (VISA-P) intrasubject effects.

Measure	Asymptomatic Knee Group (n = 15)	Symptomatic Knee Group (n = 13)	Intrasubject Effects	
			Time Value F (Df); P (Eta2)	Intervention X Time F (Df); P (Eta2)
ROM (°)			F (3,78) = 47.998; $p = 0.001$ (0.649)	F (3,78) = 0.387; $p = 0.70$ (0.763)
Baseline	129.0 ± 11.70	133.5 ± 6.4		
Post-intervention				
24 h	137.0 ± 6.50 *	140.6 ± 5.70 *		
1 week	142.2 ± 7.19 *	147.0 ± 5.10 *		
1 week	146.2 ± 6.50 *	148.5 ± 4.50 *		
NRS			F (3,78) = 11.562; $p = 0.001$ (0.308)	F (3,78) = 0.725; $p = 0.54$ (0.027)
Baseline	56.4 ± 14.56	56.9 ± 18.88		
Post-intervention				
24 h	48.3 ± 17.19	45.8 ± 23.08		
1 week	42.8 ± 17.64	40.6 ± 16.77		
1 week	42.3 ± 23.10	33.1 ± 21.05 *		
Kujala score			F (3,78) = 6.835; $p = 0.001$ (0.208)	F (3,78) = 3.043; $p = 0.05$ (0.105)
Baseline	78.8 ± 10.60	73.2 ± 6.70		
Post-intervention				
24 h	80.8 ± 10.90	77.2 ± 8.96		
1 week	82.7 ± 9.90	80.0 ± 10.70		
1 week	82.9 ± 12.00	84.5 ± 9.10 *		
VISA-P score			F (3,78) = 4.054; $p = 0.01$ (0.135)	F (3,78) = 2.044; $p = 0.11$ (0.073)
Baseline	59.0 ± 12.90	50.2 ± 18.90		
Post-intervention				
24 h	66.7 ± 13.30	55.1 ± 15.30		
1 week	66.1 ± 11.40	52.9 ± 14.40		
1 week	63.4 ± 16.20	60.9 ± 17.50		

Values are mean ± SD unless otherwise indicated. Abbreviations: ROM, range of motion; NRS, numeric ratio scale. * Bonferroni correction values for the intrasubject (time) effects. Significant differences from baseline. p -values ($p < 0.05$).

4. Discussion

The aims of this study were to examine the short-term and crossover effects of US-guided PNM in patients with unilateral AKP. The main finding of this study was that a single-shot percutaneous femoral nerve stimulation may cause an improvement in pain, knee flexion ROM, and knee functionality, with a significant improvement after 1 week following intervention. Compared to both groups, patients who were treated with neuromodulation in the femoral nerve of the painful knee were more likely to report at least significant change in Kujala and NRS scores at 1 week following intervention. However, the therapeutic benefits were produced independently of the stimulated femoral nerve. In line with this [21], these results confirmed the crossover effect of this technique because the US-guided PNM had a great effect on the painful knee when delivered to the contralateral limb. The data of this study showed the crossover effect of the PNM intervention regarding knee flexion ROM, but also pain and functionality.

The application of electrical stimulation in the peripheral nervous system has historically required surgical intervention, carrying a risk of nerve damage stemming from implanted devices [29,30]. Transcutaneous electrical nerve stimulation has been used in an attempt to address this limitation, but it has been unsuccessful [31]. A percutaneous nerve stimulation approach is under clinical investigation, which is designed to address these needs and allow treatment of the nerve. The use of ultrasound has allowed the development of percutaneous peripheral nerve stimulation. On the one hand, some therapists implant a percutaneous peripheral nerve stimulator to manage chronic pain, such as radiculopathy pain [32], neuropathic postamputation pain [33], or low back pain [34]. On the other hand, other clinicians use the US-guided PNM that allows for applying PES in close proximity to the nerve, with ultrasound guidance [13]. US-guided PNM has been found to be an effective technique for the treatment of chronic pain conditions [14,35,36] and muscle strength in subjects with previous unilateral knee pain [15] and with short hamstring syndrome [21], as well as for the improvement of healthy dancers' performance [28].

To the best of the authors' knowledge, this is the first study to demonstrate the short-term effects of a PNM intervention in patients with AKP. The relevance of this finding for clinical practice is that a simple single-shot of US-guided PNM in the femoral nerve in patients with a painful knee produces effects that are significant for a week following the treatment (Table 2). These results are in line with a previous study [14] that demonstrated the immediate effects of this procedure on pain and knee flexion ROM in patients with AKP. Therefore, as a methodological recommendation, authors suggest that the technique may be employed once a week. Further research is necessary to elucidate the relative benefits and methodological procedure of US-guided PNM in treating chronic pain. In addition, US-guided PNM is a well-tolerated and safe procedure that may be applied in patients with AKP, and other conditions [36,37]. In fact, there were no symptoms such as postpuncture pain, and adverse events disappeared within 24 h.

Finally, to the best of our knowledge, no studies have demonstrated the crossover effect of US-guided PNM in the femoral nerve. These results corroborated the findings from studies that examined crossover effects of other techniques on the contralateral limb [16–20], including neural therapy [21]. The authors reaffirm that the neural system has a connection throughout the body and it is likely that the neural treatment on one limb may cause crossover effects on the contralateral limb.

The current study has some limitations. Firstly, the authors did not take into account the underlying pathology of the patients with AKP. It is possible that different musculoskeletal injuries may provide information of clinical interest. Secondly, the study did not include a control group to analyze the placebo effect and this may be an appropriate comparator. Thirdly, the convenience sample was only based on one study, which could be slightly reflected in the results. Future studies are necessary to clarify the methodology for applying the US-guided PNM technique, for example, comparing the effectiveness of ultrasound-guided procedures with unguided interventions.

Clinical Relevance

The findings of the present study showed the therapeutic effects of US-guided PNM, which are significant for a week following the intervention, independently of the intervention limb. Therefore, clinicians should know that:

1. US-guided PNM may be an effective therapeutic procedure for patients with AKP;
2. US-guided PNM causes not only a local effect on the target tissue, but also a distal effect (in this case, a crossover effect);
3. One single-shot PNM intervention per week may be enough.

5. Conclusions

A single-shot US-guided PNM intervention per week in the femoral nerve may be an effective treatment for improving the pain, knee flexion ROM, and knee functionality. In addition, this technique produces crossover benefits in the nonintervention limb.

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