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High voltage pulsed galvanic stimulation adjunct to rehabilitation program for patellofemoral pain syndrome: a prospective randomized controlled trial

Defne KAYA, İnci YÜKSEL, Michael James CALLAGHAN, Hande GÜNEY, Özgür Ahmet ATAY, Seyit ÇITAKER, Gazi HURI, Onur BILGE, Mahmut Nedim DORAL

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Research Article

D Kaya
Hacettepe U, Faculty of Medicine, Dept of Sports Med, Ankara, Türkiye
PT, PhD

İ Yüksel
Hacettepe U, Faculty of Health Sciences, Dept of Physiotherapy and Rehabilitation, Ankara, Türkiye
PT, PhD, Prof

MJ Callaghan
Centre for Rehabilitation Science, University of Manchester, Royal Infirmary, M13 9WL, Manchester, Great Britain
PT, PhD

H Güney
Hacettepe U, Faculty of Health Sciences, Dept of Physiotherapy and Rehabilitation, Ankara, Türkiye
PT, MSc

ÖA Atay, MN Doral
Hacettepe U, Faculty of Medicine, Dept of Orthopedics and Traumatology, Ankara, Türkiye
MD, Prof

S Çitaker
Gazi U, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Ankara, Türkiye
PT, PhD, Assist Prof

G Huri, O Bilge
Hacettepe U, Faculty of Medicine, Dept of Orthopedics and Traumatology, Ankara, Türkiye
MD

Address correspondence to:
Defne Kaya, PT, MSc, PhD, Lecturer
Dept of Sports Medicine, Faculty of Medicine, Hacettepe U, 06100, Ankara, Turkey
E-mail: defne@hacettepe.edu.tr

Purpose: The aim of this study was to investigate the effectiveness of High Voltage Pulsed Galvanic Stimulation (HVPGS) in conjunction with patellar taping on pain and functional levels of patients with Patellofemoral Pain Syndrome (PFPS). **Methods:** This study was designed as a prospective randomized controlled study. Forty-five female patients with unilateral symptomatic PFPS were randomly allocated into three groups. All patients were treated with a standard rehabilitation program. In addition, Group-1 received HVPGS in conjunction with patellar taping, Group-2 received HVPGS, and Group-3 received patellar taping. All treatments were applied for six weeks. Pain levels during step-up and step-down activities were measured. Lower Extremity Functional Scale (LEFS) was utilized to determine functional level. All tests were done before and after the treatment. **Results:** There were differences in pain levels during step-down ($p=0.01$) and during step-up ($p=0.02$) between Group-1 and 3 and during the step-up activities ($p=0.02$) between Group-2 and 3 after the treatment. There were no significant differences in functional level between the groups after the treatment ($p>0.05$). The groups that included HVPGS (Group-1 and 2) had better pain scores during step-up and down activities as compared to Group-3. **Conclusion:** Additional HVPGS application in PFPS rehabilitation may decrease in pain levels during activities including step up and down while functional status remains the same.

Keywords: Patellofemoral pain syndrome, Knee, Electrical stimulation, Athletic tape.

Patellofemoral ağrı sendromu rehabilitasyonuna eklenen yüksek voltaj kesikli galvanik stimulasyon: prospektif randomize kontrollü çalışma

Amaç: Bu çalışmanın amacı patellar bantlama eşliğinde uygulanan yüksek voltaj kesikli galvanik stimulasyonun (YVKGS), patellofemoral ağrı sendromu (PFAS) olan hastalarda ağrı ve fonksiyonel seviyeye etkisini incelemekti. **Yöntem:** Bu çalışma, prospektif randomize kontrollü olarak 2006-2008 yılları arasında Hacettepe Üniversitesi'nde gerçekleştirildi. Tek taraflı semptomatik 45 PFAS'li kadın rastgele üç gruba dağıtıldı. Grup 1'e standart rehabilitasyona ek olarak bantlama eşliğinde YVKGS, Grup 2'ye standart rehabilitasyona ek olarak YVKGS ve Grup 3'e ise standart rehabilitasyona ek olarak patellar bantlama yapıldı. Tüm tedaviler altı hafta boyunca uygulandı. **Sonuçlar:** Tedavi sonrasında, Grup 1 ile 3 arasında merdiven inme ($p=0.01$) ve çıkma ($p=0.02$) sırasında oluşan ağrıda ve Grup 2 ile 3 arasında merdiven çıkma ($p=0.02$) ağrısında fark bulundu. Fonksiyonel seviye açısından gruplar arasında fark bulunmadı. Tedavi programına YVKGS eklenen grupların (Grup 1 ve 2) merdiven inme ve çıkma sırasındaki ağrısı Grup 3'e oranla daha iyiydi. **Tartışma:** PFAS rehabilitasyonuna eklenen YVKGS, merdiven inme ve çıkma gibi aktivitelerdeki ağrıyı azaltmaya yardım etmesine rağmen fonksiyonel seviyeye etkisi yoktur.

Anahtar kelimeler: Patellofemoral ağrı sendromu, Diz, Elektrik stimulasyonu, Bantlama.

Neuromuscular re-training of the Vastus medialis (VM) in patients with Patellofemoral Pain Syndrome (PFPS) includes therapeutic exercises with braces, biofeedback, manual therapy techniques and patient education.[1-8] McConnell,[9] investigated the patellar taping techniques to create a mechanical realignment of the patella thus centralizing it within the trochlear groove and controlling patellar tracking.[9,10] It has been shown that taping relatively increases the activity level of the VM compared to Vastus lateralis (VL),[3,4,11] and also increases quadriceps strength,[1] enhances neuromuscular recruitment,[9] and reduces pain.[12,13]

Electrotherapy is widely used for retraining of the VM in rehabilitation programs of the PFPS.[5,6,10,14-20] Especially, High Voltage Pulsed Galvanic Stimulation (HVPGS) is an effective method for the stimulation of the muscle fibers.[6,10,14] The strength-duration curve of HVPGS includes short pulses at high intensities which lead to stimulate selectively motor nerves instead of sensory nerves of pain.[21,22] Therefore, HVPGS has been used for muscle strengthening and the reduction atrophy of innervated muscle.[21,22]

Since the association between the abnormal tracking of patella and quadriceps muscle weakness has been established in PFPS, there has been growing interest in developing different treatments.[2,4,5,8,12,14-20] Several researchers have identified the importance of HVPGS,[6,12,14-20] and the taping techniques[3,4,9,11,13,] in PFPS rehabilitation for re-education of VM and the correction of patellar position. However, limited scientific evidence is available regarding the effectiveness of the combination of these treatment techniques.

We believe that an application of a combined HVPGS and patellar taping would result in greater pain levels and functional status. Despite the evidence from the comparison of the single application of these treatment techniques on PFPS, we could not find any studies comparing those three different treatment techniques. The purpose of this study was to investigate the best treatment technique for reducing pain and increasing functional levels of PFPS patients. Therefore, we decided to use three different treatment protocols: Group-1 was applied standard rehabilitation and HVPGS in conjunction with patellar taping, Group-2 was applied standard rehabilitation and HVPGS, and Group-3 was applied standard rehabilitation and patellar taping, respectively.

METHODS

Design: This randomized controlled study was designed to evaluate the effects of HVPGS in conjunction with patellar taping on pain level and functional score in patients with PFPS.

Patients: Forty-five female patients with unilateral symptomatic PFPS were included in this study. Patients were informed about the study and a written informed consent was obtained.

Patients were included in the study if (1) the onset of pain was longer than six months, (2) the presence of retropatellar pain, crepitation and pain in patellar grinding, (3) the ages between 18-40 years and (4) there were no abnormalities on magnetic resonance imaging.

Patients were excluded from the study if (1) there were history or clinical evidence of patellofemoral dislocation, subluxation, or osteoarthritis, (2) the presence in the clinical examination of injury or dysfunction to the knee ligaments, bursae, menisci, and synovial plicae, (3) there were history of lower extremity surgery and (4) there were radiographic evidence of osteoarthritis in any compartments of the knee joint.

Using data from Whittingham et al. [23], sample size was calculated on the basis of the Visual Analogue Scale (VAS) pain scores and should detect a 10% change at a significance level of 0.05 and 90% power. These criteria lead to an estimated minimum sample size of 10 in each group.[23] Demographic information of the patients are shown in Table 1.

Evaluation Parameters

Pain: VAS (0-100 mm) was used for the pain assessment. 0 point indicated no pain and 100 points indicated severe pain. Pain was assessed during step up and down from a standard 20.3cm

gym bench and also in full squat position.

Functional Level: Functional level was assessed by using Lower Extremity Functional Scale (LEFS).[24] The LEFS is reliable and construct validity was supported by comparison with the SF-36, and test-retest reliability was found excellent (r=0.94 [95% lower limit confidence interval (CI)=0.89])[24] and widely used in the PFPS patients.[25,26,27] The LEFS consists of 20 items each with a maximum score of 4. The total score of 80 indicates a high functional level.[24]

Pain and functional level assessment were performed pre-treatment and six weeks after the treatment.

Randomization

The patients were randomly allocated into three groups by the second author who was blinded in measurements and assessments.

Procedures

Each group treated for six weeks. Standard rehabilitation-exercises program was performed by patients in all groups.

Group-1: Standard rehabilitation-exercises program plus The HVPGS in conjunction with patellar taping was performed. The HVPGS in conjunction with patellar taping was applied 20 minutes and five sessions in a week during six weeks.

Group-2: Standard rehabilitation-exercises program plus the HVPGS was performed. The HVPGS was applied 20 minutes and five sessions in a week during six weeks.

Group-3: Standard rehabilitation-exercises program plus patellar taping was performed. A self-application education was given to the patients about how to apply the taping corrections and they were instructed to wear the tape during the daily activities. Patients applied the taping every day, during the exercises. Patients in the standardized rehabilitation program were prescribed daily home exercises and taping was checked once per week in the orthopedic rehabilitation department.

Physical Therapy Interventions

Patellar Taping: The patients were treated by a physiotherapist trained in the patellar taping technique described by McConnell to correct patellar malposition.[9,10] First an sub-tape (M-Wrap ®, 70mm X 27.5 mm, Mueller®, USA) was applied, while taking care of not to place any tension on the patient's skin. After the application of a sub-tape, a corrective tape (Protape ®, 38 mm X 10 m, Norway) was applied. Corrections were applied to obtain anterior tilt, medial glide, medial tilt, and unloading the fat pad until the patient's pain was reduced at least 50%.[9]

Standard rehabilitation-exercise program: A standard home exercise program for PFPS was developed based on the literature.[9,21,22] The program included the neuromuscular retraining exercises included isometric quadriceps exercises in sitting, straight leg raise exercises (neutral position) with ankle weights, terminal knee extension exercises with ankle weights, wall squats with ball between the knees, split squats with Theraband® Stability Trainer (blue color), step-down exercises (backward, forward and sideway), and single-leg balance exercises in different knee angle with Theraband® Stability Trainer (blue color). Stretching exercises included quadriceps, iliotibial band, hamstrings, and gastrocnemius muscles.

High Voltage Pulsed Galvanic Stimulation: A portable galvanic stimulator with monophasic (twin-peak pulse) waveform and pulse duration of 65-75 μs was used in this study. The intensity amplitude of the HVPGS ranges from 0 to 300 V. Within the pulse frequency options available on the HVPGS, 60 pps was selected for strengthening VM.[28] The proximal electrode (4x4cm) was placed 4 cm superior to the supero-medial border of the patella, and the distal electrode (4x4cm) was placed 3 cm medial to the first point in order to stimulate of VM as described by Basmajian and Blumenstein.[29] The HVPGS was applied while the patients were sitting with their knees extended, and they were ordered to perform quadriceps isometric exercise with the stimulation. The intensity of stimulation was adjusted a strong contraction without causing patellofemoral pain.

Statistical analysis:

Normality of the distribution of the data was investigated using Kolmogorov-Smirnov testing

with alpha set at 0.05. This testing confirmed that the data were normally distributed and that further statistical analyses using the parametric testing would be appropriate. All data were analyzed using the Statistical Package for the Social Sciences (SPSS®) version 14.0. The independent sample t tests were used to investigate the differences between groups. Statistical significance was set at 0.05.

RESULTS

All patients completed the rehabilitation program and all assessment procedures.

Pain: Pre-post treatment pain levels are given in Table 2. There were significant differences in VAS levels during the step-down, F=7.259, p=0.01; step-up, F=6.003, p=0.02, while there was no significant difference during squat, F=1.432, p=0.24 between Group 1 and 3 after treatment. There were no significant differences in VAS levels (during the step-down, F=1.764, p=0.19; step-up, F=0.001, p=0.98; squat, F= 1.397, p=0.25) between Group 1 and 2 after treatment. There was significant difference in VAS levels during step-up (F=6.258, p=0.02) while there were no differences in step-down (F=2.696, p=0.11); and in squat (F=1.122, p=0.29) between Group 2 and 3 after treatment (Table 3). Pain during step down activity was significantly decreased after the application of HVPGS in conjunction with patellar taping. In addition, application of HVPGS with standard rehabilitation was also decreased the pain levels of step up activity.

Functional Level: Pre and post treatment pain levels were given in Table 2. There were no significant differences in LEFS scores (F= 1.397, p=.25) between Group 1 and 2, (F= 1.605, p=.21) between Group 2 and 3, (F= 0.068, p=.79) between Group 1 and 3 after the treatment. (Table 3). Functional levels were similar in all treatment groups (p>0.05).

DISCUSSION

This was the first study to investigate the effects of HVPGS in conjunction with patellar taping on pain and functional levels in patients with PFPS. Our hypothesis was that HVPGS in conjunction with patellar taping would lead better re-education of VM in a corrected patellar position. To our knowledge, there is no randomized controlled study which investigates the effectiveness of HVPGS during the application of patellar taping.

The principal finding was there was no significant difference in VAS level, in squat position and also in functional level between the groups at the end of the treatment. Similar results has been noted in previous studies.[30,31] In all groups, the pain score during the activities decreased and these results indicates that there were no significant differences between the different physical therapy programs. The present study also demonstrated that an exercise program in conjunction with short- period patellar taping for six weeks was effective in pain and functional levels in PFPS patients.

Researchers have identified the importance of the use of electrical muscle stimulation of quadriceps especially on VM in patients with PFPS.[14-20] Only two articles were methodologically robust, with comparative control groups with proper randomization methods.[16,17] Nevertheless, none of these studies showed between group differences even though there was evidence that electrical muscle stimulation was beneficial to PFPS.

We found two randomized controlled trials which assessed the effect of electrical stimulation of quadriceps in the treatment of PFPS.[16,17] In the first study, Callaghan et al. compared two different type of electrical stimulation in PFPS patients with quadriceps atrophy.[16] Experimental group received a new type of electrical stimulation which produced a balanced, asymmetrical biphasic pulse to a maximum of 90 mA with duty cycle: 10 sec stimulus-50 sec pulse, and the pulse duration was set at 200 μs. Standard stimulation group received an electrical stimulation which generated bipolar, biphasic, and asymmetrical rectangular pulses. They treated the patients once a day for five days during a week for the first two weeks (2 minutes at 8 Hz pulse width 250 μs; 20 minutes at 35 Hz pulse width 350 μs; 3 minutes at 3 Hz pulse width

Table 1. Demographic variables of the patients.

	Group 1 (N=15) Mean±SD	Group 2 (N=15) Mean±SD	Group 3 (N=15) Mean±SD
Age (years)	45.9±6.8	46.4±7.2	39.5±12.4
Body weight (kg)	72.0±9.4	73.5±11.8	63.2±8.7
Height (cm)	163.4±8.4	164.0±10.8	168.7±10.3

Table 2. Pre- and post-treatment pain (VAS, mm) and Lower Extremity Functional Scale (LEFS) scores of the groups.

	Group 1 (N=15)		Group 2 (N=15)		Group 3 (N=15)	
	Pre-treatment Mean±SD	Post-treatment Mean±SD	Pre-treatment Mean±SD	Post-treatment Mean±SD	Pre-treatment Mean±SD	Post-treatment Mean±SD
Pain (VAS, mm)						
Step-down	60.66±10.00	37.12±17.18	62.53±5.67	41.53±11.74	39.47±36.49	3.97 ± 7.54
Step-up	68.53±10.87	34.93±18.69	68.13±9.73	37.06±18.65	49.47±35.71	3.40±9.44
Squat	89.40±19.27	20.21±12.54	92.87±15.87	15.15±15.17	71.73±23.75	14.47±26.63
LEFS	40.87±14.22	73.13±8.41	38.80±16.65	64.20±18.85	50.06±15.88	72.40±8.58

Table 3. Group differences of pain (VAS, mm) and Lower Extremity Functional Scale (LEFS) scores after treatment.

	Pain (VAS, mm)						LEFS	
	Step-up		Step-down		Squat			
	F	p	F	p	F	p	F	p
Group 1-2	7.259	0.01*	6.003	0.02*	1.432	0.24	1.397	0.25
Group 2-3	1.764	0.19	0.001	0.98	1.397	0.25	1.605	0.21
Group 1-3	6.258	0.02*	2.696	0.11	1.122	0.29	0.068	0.79

*p<0.05.

250 μs). For the last two weeks, treatment was applied three times a week (2 minutes at 8 Hz pulse width 250 μs; 20 minutes at 45 Hz pulse width 350 μs; 3 minutes at 3 Hz pulse width 250 μs). Although both groups showed significant improvements in VAS levels, muscle strength, Kujala patellofemoral score, step test, cross-sectional area of quadriceps muscle, except degree of knee flexion range and muscle fatigue of quadriceps, there were no statistically significant difference between the two types of stimulation.[16] In their second study, the authors randomized 80 patients into two groups.[17] First group received a new form of electrical muscle stimulation incorporating simultaneously delivered frequency components of 83 Hz, 50 Hz, 2.5 Hz, and 2 Hz

with a doublet of pulses (125 Hz) at the beginning of each pulse train. Daily stimulation applied 60 minutes in total. The second group received a standard electrical stimulation for 60 minutes with the same frequency of 35 Hz. Both groups showed significant improvements in the VAS, Kujala Patellofemoral score, step test, degree of knee flexion range, cross-sectional area of quadriceps muscle, muscle fatigue of quadriceps and isometric and isokinetic torque of quadriceps muscle: these improvements did not differ significantly between the groups.[17] The authors indicated in both studies that the different types of stimulations would lead improvements in pain and functional levels and electrical stimulation might be one of the options of the treatment of the PFPS. Improvements of the pain and functional level results in the present study were in agreement with the Callaghan et al., however, the groups which applied stimulation had better pain scores in step-up and step-down activity. [17]

Whitelaw et al.[20] applied electrical muscle stimulation of quadriceps, ice application, exercises and non-steroidal anti-inflammatory medication to the patients with PFPS. They found that 57% of patients increased in knee function levels, 35% of the patients stayed at the same level, and 8% decreased in functional levels (mean duration of follow up was 16 months).[20] In addition, Werner et al,[19] found differences in functional knee score, isokinetic quadriceps strength, and cross sectional area of VM before and after 10 weeks application of transcutaneous electrical stimulation of the VM and stretching of the lateral thigh muscles in patients with PFPS.[19] The authors also indicated that, no differences were found in the cross sectional area of VL and position of patella after treatment.[19] Tunay et al. treated 80 patients with PFPS into four groups.[18] The first group received an application of ice, electrical nerve stimulation, patellar taping and exercise. The second group received an application of ice, electrical nerve stimulation, medial patellar glide and exercise. The third group received an application of ice, patellar taping and home exercise. The last group received an application of ice and home exercise. Although all groups showed significant improvements in pain score, patellar tilt angle with the use of Magnetic Resonance Imaging (MRI), Q angle, Cincinnati Knee Activity Rating Scale, hamstring and iliotibial band flexibility, thigh circumference measurement, and leg-length discrepancy, there were no statistical difference in the sulcus angle in MRI. The authors indicated that results between in the first and second groups were significantly better than in the third and fourth.[18]

In another randomized study, Bily et al.[15] compared supervised physical therapy (PT) training with the application of PT and Electric Muscle Stimulation (EMS). EMS was applied to the knee extensors for 20 minutes, 2 times daily, 5 times a week for 12 weeks at 40 Hz, with pulse duration of 26 msec, stimulation period at 5 seconds and rest period at 10 seconds. The authors found a significant reduction of pain and improvement of the Kujala Patellofemoral score in the both groups. They also indicated that no differences were found between the two treatment groups.[15]

Different EMS procedures were used in the literature while the results were conflicting because of the lack of randomized controlled trials. There was only one randomized controlled study investigated the effectiveness of HVPGS in PFPS patients.[14] Akarcalı et al., compared the application of HVPGS on VM and exercise program with the application of only exercise program that included isometric and eccentric quadriceps exercises for six weeks.[14] Their results showed improvements in the pain score and muscle strength while improvements did not differ between the groups at the sixth week. The authors pointed out that pain reduction in the first group was greater than the second group at the third week. The main outcome of this previous pilot study was HVPGS helps to decrease the pain levels at the early weeks of rehabilitation program.[14] In the present study, there were differences in pain during step-up and down activities between the supervised rehabilitation groups (Group 1 and 2) compared to the standard home rehabilitation group (Group 3) while there were no differences in functional levels between the groups after the treatment.

These results were partially in agreement with the results of Akarcalı et al.[14] Although improvements in pain level during step-up and down were better in the Group 1 and Group 2 that include HVPGS. Therefore, the present study indicates that HVPGS application decreases pain in patients with PFPS. Another important outcome was the functional levels were similar between all groups. We emphasized that rehabilitation program including the self application of the taping would also beneficial for the patients with PFPS.

Limitations of the present study: The primary limitation of our study was that, although we had the opportunity to compare each groups with an age-matched healthy population, we were not able to assess our parameters. Another limitation was that the present study did not assess the long-term efficacy of treatment. A further issue was that this study was unable to assess quadriceps muscle strength and electromyographic (EMG) activity of the VM and VL.

The results showed that HVPGS application decreases pain in some activities in PFPS patients. The similar results were found in functional level in both of the groups after the treatment. Further investigation is needed to determine if HVPGS application in conjunction with patellar taping improves EMG activity of VM in patients with PFPS. In addition, a longitudinal, prospective study on a large healthy, asymptomatic cohort would help to address this issue.

Conflict of interest statement: All authors have no conflicts of interest with respect to the data collected and procedures used within this study.

Ethical statement: The authors confirm this study meets the guidelines of the Declaration of Helsinki, and after local ethical approval all patients provided written informed consent. Ethical approval for the study was received from Hacettepe University in Turkey. Number is HEK 07/134-5.

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