Randomized Trial

Conservative Treatment Versus Ultrasound-Guided Injection in the Management of Meralgia Paresthetica: A Randomized Controlled Trial

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Background: Meralgia paresthetica (MP) is an entrapment mononeuropathy of the lateral femoral cutaneous nerve (LFCN), in which conservative treatment options are not always sufficient.

Objectives: The aim of this study was to evaluate the efficacy of ultrasound (US)-guided LFCN injection in the management of MP by comparing with transcutaneous electrical nerve stimulation (TENS) therapy and sham TENS therapy.

Study Design: A prospective, randomized, sham-controlled study.

Setting: Health Sciences University Training and Research Hospital in Turkey.

Methods: Patients diagnosed with LFCN compression with clinical and electrophysiological findings were included in this study. Patients were randomly assigned to 3 groups: (1) US-guided injection group, (2) TENS group, and (3) sham TENS group. The blockage of the LFCN was performed for therapeutic MP management in group 1. Ten sessions of conventional TENS were administered to each patient 5 days per week for 2 weeks, for 20 minutes per daily session in group 2, and sham TENS was applied to group 3 with the same protocol. Visual Analog Scale (VAS), painDETECT questionnaire, Semmes-Weinstein monofilament test (SWMt), Pittsburgh Sleep Quality Index (PSQI), and health-related quality of life (36-Item Short Form Health Survey [SF-36]) at onset (T1), 15 days after treatment (T2), and 1 month after treatment (T3) were used for evaluation. Patients and the investigator who evaluated the results were blinded to the treatment protocol during the study period.

Results: A total of 54 of the 62 patients (group 1 n = 17, group 2 n = 16, group 3 n = 21) completed the study, 3 patients from group 1, 4 patients from group 2, and 1 patient from group 3 dropped out during the follow-up period. The mean changes in painDETECT and SWMt scores showed a statistically significant difference between groups in favor of group 1 at T2 and T3 compared with T1 ($P < 0.05$). There was no statistically significant difference between groups in terms of VAS, SF-36, and PSQI scores ($P > 0.05$). In-group analysis of VAS scores showed a statistically significant decrease in T2 and T3 compared with T1 in group 1 ($P < 0.05$). In-group analysis of the VAS scores statistically significant decrease was shown in T2 compared with T1 in group 2 ($P < 0.05$). In-group analysis of painDETECT scores statistically significant decrease was shown in T2 and T3 compared with T1 in all groups ($P < 0.05$). In-group analysis of SWMt scores statistically significant decrease was shown in T2 and T3 compared with T1 in group 1 ($P < 0.05$). In-group analysis of SF-36 and PSQI scores, there was no statistically significant decrease in all groups ($P > 0.05$).

Limitations: The limitation of the study was a short follow-up period.

Conclusions: US-guided LFCN injection and TENS may be therapeutic options for MP treatment, however, for patients with neuropathic pain symptoms, US-guided LFCN injection may be a safe and alternative method to conservative treatment.

Key words: Meralgia paresthetica, ultrasound-guided injection, transcutaneous electrical nerve stimulation

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Meralgia paresthetica (MP) is an entrapment neuropathy of the lateral femoral cutaneous nerve (LFCN), characterized by paresthesias and numbness at the anterolateral side of the thigh (1,2). MP has an incidence of 4.3/10.000 and usually affects people aged 30 to 40 years (3).

Treatment strategies for MP are mainly divided into conservative and interventional therapies (1). Conservative therapy is successful in 4 to 6 months in 85% of cases (4-6). The first conservative management involves avoiding pressure generating activities, such as losing weight or wearing tight clothing. Pharmacologic treatment should be initiated in resistant patients (1). Another option is nonspecific physical therapy, which includes heat band and ice sac application, transcutaneous electrical nerve stimulation (TENS), interventional current, and therapeutic ultrasound (US) to the lateral portion of the inguinal ligament (7,8). There is a need for safe, practical, economical, and new techniques with fewer side effects in patients with MP who are resistant to treatment or have not tolerated treatment. Recently, as an interventional treatment option, the peripheral nerve block of the LFCN by US guidance has been described. There are anatomic points concerning the injection site of the LFCN block but considering the 30% anatomic variability of the LFCN, the possibility of failure of injection into the LFCN blocks reaches up to 60% (4,9-11). US is a practical and powerful tool for imaging peripheral nerves, allowing noninvasive evaluation of morphological changes and anatomic variations. US-guided LFCN blocks enable effective, economical, and safe treatment techniques for MP (10,12). To date, in a few case series and studies, the effect of US-guided LFCN blocks for MP have been investigated, but there is no randomized controlled trial evaluating the efficacy of LFCN blocks for MP treatment (13-17). TENS is a safe physical therapy approach that aims to reduce pain by inhibiting nociceptors, blocking the transmission of pain in the afferent nerve or sympathetic system control and opioid release (18-19). TENS may be a conservative approach in the management of patients with MP. Many studies have investigated the effect of TENS in entrapment neuropathies of the upper extremities (18-20). There are no reported studies regarding the efficacy of TENS therapy in MP. The aim of this study was to evaluate the conservative treatment versus US-guided injection in MP management.

Methods

Study Design and Patients

A randomized, prospective, single-blind, sham-controlled study was conducted. Patients diagnosed with LFCN entrapment confirmed by clinical (Tinel sign and sensory examination) and electrophysiological findings were included in this study.

Patients with secondary entrapment neuropathy (e.g., diabetes, inflammatory arthritis, hypothyroidism), malignancy, pregnancy, skin infection in the inguinal region or dermatitis, lumbar radiculopathy, polyneuropathy, and cardiac pacemakers were excluded. Patients with a history of TENS therapy and patients who had received corticosteroids or injection of local anesthetic medication for MP up to 3 months prior were excluded from the study. Written informed consent was obtained from all patients, and all procedures were carried out in accordance with the Declaration of Helsinki of 1975, approved by the local organization's clinical research ethics committee (2014/29). This trial was registered at www.clinicaltrials.gov. Trial Registration: NCT04004052.

The patients were randomly assigned to 1 of 3 groups using a secure system with numbered opaque and sealed envelopes numbered 1 to 3. Group 1 received local anesthetic and steroid injection (n = 17), group 2 TENS treatment (n = 16), and group 3 sham TENS treatment (n = 21).

In the injection group (group 1), a US-guided LFCN block was applied. There is no standard procedure for the injection site, therefore the method suggested by Tagliafico et al (14) was used. The patient was placed in the supine position. The injection was performed with a 7- to 13-MHz linear array transducer (LOGIQ P5, GE Healthcare, Little Chalfont, Buckinghamshire, UK). Anterior-superior iliac spine (ASIS) is the reference point that is examined and visualized by the US probe. The transducer was located at the ASIS level on the painful iliac region. The lateral end of the probe was placed on the ASIS, and the medial portion of the probe was caudally oriented so that the transducer became parallel to the inguinal ligament. While the operator searches for the LFCN echo sign, the transducer is moved slightly in the mediocaudal direction. The LFCN is seen as a small structure in the short axis view medial to the ASIS (Fig. 1). The 22-gauge needle was placed in the lateral to medial orientation along the subcutaneous tissue. One milliliter of betamethasone disodium phosphate (5 mg/mL) and 2 mL of prilocaine (2%) was injected with US guidance around the LFCN.

Group 2 and group 3 TENS therapies were provided

by the same experienced physiotherapist. The physical therapist was aware of the patient groups, and used TENS stimulation procedures with 2 channels and 4 outputs using the same device (ITO ES320, MDALL 66503, Tokyo, Japan). TENS/sham TENS treatment was applied to the painful anterolateral thigh target (TENS electrodes 5 x 5 cm wired, self-adhesive). The stimulation pulse frequency is set to 100 Hz, and the pulse width is 100 ms (conventional TENS). In the TENS group, the excitation force was kept below the motor threshold to induce tingling sensation in the stimulated area without muscle twitching or pain. In the sham TENS group, no current was applied to the patient. TENS therapies were applied to each patient for a total of 10 sessions. The sessions lasted 2 weeks (5 sessions per week, 20 minutes per session). All sessions were performed in the hospital and by the same physiotherapist. The physiotherapist was not the person who evaluated it. Patients and the investigator who evaluated the results were blinded to the treatment protocol during the study period.

Outcome Measures

The outcomes are the pain, cutaneous pressure threshold measurement, quality of life, and sleep quality. The pain was evaluated by using the Visual Analog Scale (VAS) and painDETECT pain questionnaire. The cutaneous pressure threshold measurement was evaluated with the Semmes-Weinstein monofilament test (SWMt). Quality of life and sleep quality were evaluated using the 36-Item Short Form Health Survey (SF-36) and the Pittsburgh Sleep Quality Index (PSQI). The reliability and validity of the Turkish versions of the questionnaires were confirmed in the literature (20-22). Evaluations were performed before treatment (T1), at 15 days after treatment (T2), and at 1 month (T3) follow-up.

Statistical Analyses

IBM SPSS Statistics 22 (SPSS IBM, Istanbul, Turkey) for statistical analysis was used. The Shapiro–Wilk test was used to determine the normal distribution of the parameters. In addition to the normally distributed quantitative data and parameters, one-way analysis of variance test software was used to compare statistical data (mean, standard deviation, median, frequency, and ratio). Tukey's Honest Significant Difference test was used to identify the group that caused the difference. The Kruskal–Wallis test was used to compare 2 groups that did not show normal distribution. Variance analysis was used for in-group comparison of normal distribution parameters in repeated measurements, and the paired sample t-test

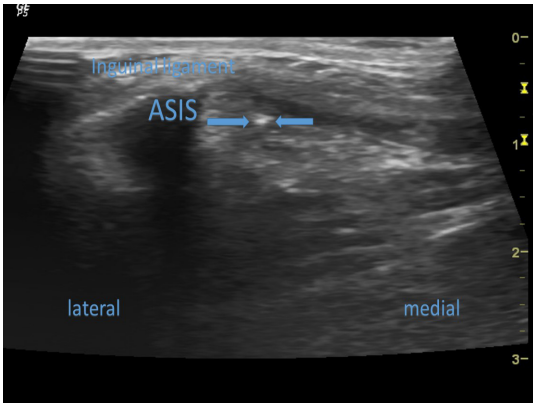

Fig. 1. *Short-axis view of the lateral femoral cutaneous nerve (LFCN, arrows). The LFCN appeared as a hypoechoic elliptical structure medial to the anterior superior iliac spine (ASIS).*

(dependent sample t-test) was used to determine the significantly different day. The Friedman test was used for the in-group evaluation of variables with nonnormal distribution. The Wilcoxon sign test was used to determine the significantly different day. The chi-square test and the McNemar test were used to compare qualitative data. $P < 0.05$ was considered significant.

Sample Size

To determine the sample size, force analysis was performed using the G*Power 3.1.9.2 program (HeinrichHeine-University Düsseldorf, Germany). Eleven patients per group provided 80% statistical force at 5% significance level for the VAS (20) in terms of the difference between groups (effect size d = 0.587) (23). Based on those data, we concluded that a minimum of 11 patients per group would be required to achieve significant results, and 54 patients were enrolled.

Results

Seventy-seven patients were screened according to inclusion criteria. Sixty-two patients met the inclusion criteria. Fifty-four cases were included in the study (23 women and 31 men). The flow chart of the patients is presented in Fig. 2. The mean age of the study patient was 53.61 ± 11.99. The characteristics of the patients are given in Table 1.

There was no statistically significant difference between the groups in terms of demographic characteristics. Mean changes in painDETECT and SWMt scores showed a statistically significant difference in

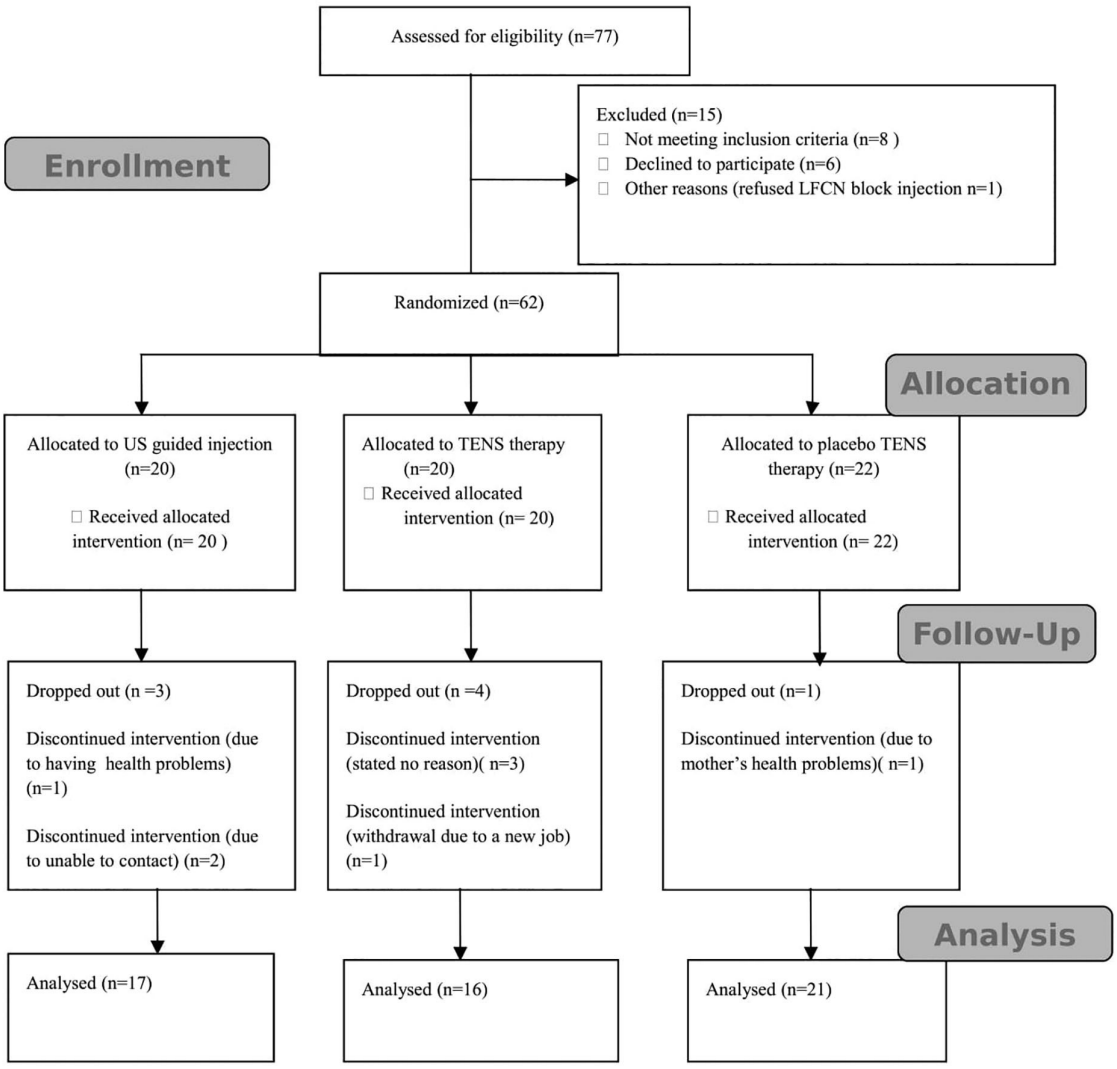

Fig. 2. *Flow diagram of patient selection process.*

T2 and T3 compared with T1 in favor of group 1 ($P < 0.05$). There were no statistically significant differences in the painDETECT and SWMt scores between the groups in favor of groups 2 and 3 ($P > 0.05$). There was no statistically significant difference between the groups in terms of VAS, SF-36, and PSQI scores ($P > 0.05$). In-group analysis of VAS scores, there was a statistically significant decrease in T2 and T3 compared with T1 in group 1 ($P < 0.05$). In-group analysis of VAS scores, there was a statistically significant decrease in T2 compared with T1 in group 2 ($P < 0.05$). In-group analysis of VAS scores, there was no statistically significant decrease in group 3 ($P > 0.05$). In-group analysis of painDETECT scores, there was a statistically significant decrease in T2 and T3 compared with T1 in all groups ($P < 0.05$). Intragroup analysis of SWMt scores showed a statistically significant decrease in T2 and T3 compared with T1 in group 1 ($P < 0.05$). In-group analysis of SWMt scores did not show a statistically significant decrease in groups 2 and 3 ($P > 0.05$). In-group analysis of SF-36 and PSQI scores did not show a statistically significant decrease in all groups ($P > 0.05$) (Table 2).

Table 1. *Demographic characteristics*.

	Group 1 n = 17	Group 2 n = 16	Group 3 n = 21	*P* value
Age (years)	51.23 ± 12.58	57.25 ± 11.17	52.76 ± 12.01	0.331
Sex (female/male)	6 (35.3%) 11 (64.7%)	10 (62.5%) 6 (37.5%)	7 (33.3%) 14 (66.7%)	0.157
BMI (kg/m^2)	29.01 ± 5.73	30.50 ± 5.54	28.54 ± 5.42	0.557
Symptom duration (months)	12.76 ± 13.98	19.37 ± 17.82	15.28 ± 25.99	0.181
Smoking	3 (17. 6%)	2 (12.5%)	5 (23.8%)	0.676
Medical treatment	2 (11. 8%)	2 (12.5%)	6 (28.6%)	0.316
Clothing Belt Corset Tight	 5 (29.4%) 0 (0%) 0 (0%)	 0 (0%) 3 (18.8%) 2 (12.5%)	 4 (19%) 3 (14.3%) 0 (0%)	0.060
Employment status Employed Official Homemaker Others	 6 (35.3%) 2 (11.8%) 5 (29.4%) 4 (23.5%)	 3 (18.8%) 0 (0%) 7 (43.8%) 6 (37.5%)	 8 (38.1%) 1 (4.8%) 6 (28.6%) 6 (28.56%)	0.598
Education Literate Primary school Secondary school High school University	 1 (5.9%) 11 (64.7%) 0 (0%) 3 (17.6%) 2 (11.8%)	 3 (18.8%) 4 (25%) 2 (12.5%) 4 (25%) 3 (18.8%)	 6 (28.6%) 7 (33.3%) 1 (4.8%) 4 (19%) 3 (14.3%)	0.330
Income Low Medium High	 7 (41.2%) 9 (52. 9%) 1 (5.9%)	 10 (62.5%) 6 (37.5%) 0 (0%)	 8 (38.1%) 10 (47.6%) 3 (14.3%)	0.364

No adverse effects or complications were observed during the follow-up period.

Discussion

MP treatment consists of preventive measures in primary care, such as avoiding activities that increase nerve compression, topical agents, anticonvulsants and antiarrhythmic medications, and various physical therapy methods (24-29). Although the treatment is generally successful without the need for surgery, there are no high-quality sham-controlled studies showing the single efficacy of the nonoperative treatment modalities (24). US-guided LFCN block has been recently described, and positive results in a small number of studies and case presentations have been presented as an alternative to surgery because they are safe and practical in patients who did not respond to conservative treatment (14,19). In our study, there was an improvement in TENS and injection groups in nociceptive pain in-group analysis. Neuropathic pain symptoms were improved in all groups.

US provides a high-resolution scan image showing the morphological changes and anatomic variability of the LFCN, and also helps visualize the spread of the drug in real-time to prevent complications during block (10,12,30-33). Another advantage of US and LFCN block is the need for relatively small amounts of solution and decreased the need for reinjection (15).

In our study, a single-dose injection of a combination of local steroid and anesthetic was performed. The main pain reduction mechanism of steroids is related to the antiinflammatory properties of steroids, and steroids also have membrane-stabilization properties through inhibition of myelinated C fiber transmission and inhibition of ectopic release (34-36). Local anesthetic drugs block A-delta and C fiber selectively, and also block sodium channels in vasoconstrictor sympathetic nerves, leading to the release of nitrous oxide (NO). NO increases vascular microcirculation and reduces inflammation (37,38). In studies regarding MP, local anesthetics and glucocorticoids were used similar to our study (10-18) because the use of this combination prolongs the duration of analgesic action (39-41). However, there is no clear consensus on the

Table 2. *Comparisons of VAS, PainDETECH score, Pittsburgh score, SMWT score, and SF-36 score within the groups, and between the groups.*

	Group 1 (Mean ± SD) (n = 17)	Group 2 (Mean ± SD) (n = 16)	Group 3 (Mean ± SD) (n = 21)	*P* value
VAS score				
T1	1.88 ± 3.06	3.31 ± 4.35	2.81 ± 3.59	0.745
T2	0.06 ± 0.25	2.25 ± 3.77	1.9 ± 3.48	0.074
T3	0.18 ± 0.53	2.5 ± 3.98	1.62 ± 3.15	0.2.66
P value	0.016**	0.046**	0.060	
PainDETECH scores				
T1	11.65 ± 7.98	14.88 ± 8.63	11.1 ± 4.77	0.500
T2	5.24 ± 5.9	11 ± 9.06	8.7 ± 5.95	0.028*
T3	4.35 ± 5.56	9.38 ± 6.47	6.41 ± 5.09	0.029*
P value	0.001**	0.004**	0.001**	
Pittsburgh score				
T1	6.94 ± 4.26	7.44 ± 4.69	6.43 ± 4.26	0.786
T2	6.06 ± 3.68	5.5 ± 3.44	6.1 ± 3.56	0.862
T3	5.94 ± 3.36	4.94 ± 3.11	4.61 ± 3.11	0.450
P value	0.289	0.128	0.140	
SMWT score				
T1	1.59 ± 1.12	2.31 ± 0.87	1.95 ± 1.36	0.158
T2	1.18 ± 1.19	2.13 ± 0.96	1.45 ± 1.19	0.049*
T3	0.82 ± 1.24	1.94 ± 1	1.5 ± 1.15	0.026*
P value	0.002**	0.196	0.064	
SF-36 PCS				
T1	41.18 ± 13.34	43.61 ± 11.34	45.71 ± 13.17	0.561
T2	41.35 ± 11.51	40.9 ± 13.55	43.34 ± 11.5	0.810
T3	42.32 ± 12.5	39.43 ± 12.43	46.74 ± 13.14	0.268
P value	0.670	0.178	0.377	
SF-36 PCS				
T1	43.28 ± 10.31	36.05 ± 10.07	38.4 ± 10. 34	0.125
T2	43.83 ± 9.86	38.88 ± 10.42	40.67 ± 10.78	0.378
T3	45.17 ± 9.99	40.87 ± 10.74	40.78 ± 14.06	0.469
P value	0.341	0.099	0.196	

T1: before treatment; T2: 15 days after treatment; T3: one month after treatment; VAS: visual analog scale; SWMT: semmes-weinstein monofilament test; SF-36 PCS: short form health survey physical component score; SF-36 MCS: short form health survey mental component score; SD: standard deviation

frequency of injections and the dose of drugs in the literature. Tagliafico et al (14) reported that 2 sessions of US-guided local steroid and anesthetic combination injection resulted in a complete recovery of pain during a 2-month follow-up. Klauser et al (15) performed US-guided local steroid and anesthetic combination injections in an average of 2.25 sessions and concluded that the 1-year follow-up of US-guided injection was consistent with pain relief. To our knowledge, this is the first sham-controlled study to evaluate the effect of single-dose US-guided combination injection with physical therapy, but the follow-up period is 1 month. In the literature, the efficacy of local glucocorticoid and anesthetic activity on peripheral neuropathy has been investigated in many studies (42-45), but studies have not shown any effect on peripheral neuropathic pain symptoms in MP. In addition to nociceptive pain, a statistically significant difference in neuropathic pain

symptoms was found in the injection group, similar to the studies in the literature. In addition, improvement in sensory complaints in the US-guided injection group was found as documented in the SWMt monofilament scores. Therefore we recommend that neuropathic pain symptoms should be evaluated in patients with MP to achieve an optimum effect on pain relief.

Bhatia et al (46) emphasized the inadequacy of secondary outcomes (sleep quality and quality of life) of perineural steroid injection in chronic pain. In addition, there is no published study evaluating the effect of local steroids on MP secondary results. In our study, there was no statistically significant difference in health-related quality of life and sleep quality scores between the groups. This result may be related to the absence of a longer follow-up period in our study, longer-term randomized controlled trials with evaluation of local corticosteroid injections at different time points should be performed in the future.

Despite the frequent use of TENS in clinical practice, there are conflicting studies about nociceptive and neuropathic pain (47-49). Gibson et al (50) emphasized in their Cochrane review that it is difficult to reach a common conclusion because of the fact that the patient population is not homogeneous in high-quality studies, and the duration, intensity, and frequency of TENS are the same. In our study, although there was a significant difference in the improvement of neuropathic pain symptoms in the injection group, compared with the TENS and sham TENS groups, intragroup evaluations showed improvement in all groups.

Limitations

There are limitations to be addressed in this study. One of the limitations is that the follow-up period might be longer. In this study, electrophysiological parameters were evaluated prior to treatment for objective assessment, and changes in electrophysiological parameters should be evaluated in future studies.

Conclusions

US-guided LFCN injection and TENS may be therapeutic options for MP treatment, however, for patients with neuropathic pain symptoms, US-guided LFCN injection might be a safe and an alternative treatment option to conservative treatment.

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All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity. Dr. Selda Kılıç, Dr. Feyza Ünlü Özkan, and Duygu Geler Külcü designed the study protocol. Dr. Gülcan Öztürk and Pınar Akpınar managed the literature searches and summaries of previous related work and wrote the first draft of the manuscript. Dr. İlknur Aktaş provided revision for intellectual content and final approval of the manuscript.

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