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# Effects of TENS Plus Exercise Treatment on Pain Level and Quality of Life in Older Adults with Diabetic Neuropathic Pain: Retrospective Study

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**Objective:** This study aimed to retrospectively evaluate the effects of Transcutaneous Electrical Nerve Stimulation (TENS) plus exercise treatment on the pain level and quality of life of older adults with diabetic neuropathic pain.

**Materials and Methods:** A retrospective review was conducted of older adults with diabetic neuropathic pain who completed 6 weeks of physiotherapy program (TENS application; 5 days a week, 20 minutes per day and various exercises like strengthening, stretching exercises, mat activities, functional activities, and range of motion exercises). The outcome measures were the body diagram, the Visual Analogue Scale (VAS), and Nottingham Health Profile (NHP).

**Results:** 16 patients participated to the study. The median age of the patients was 70 (65-83) years. When the pain levels of the patients were examined the mean, severe, the least, and current pain levels of the patients decreased ($P<0.05$), and according to NHP scores it was observed that the pain, emotional reactions, sleep subscales, and total NHP points decreased meaningfully after the treatment ($P<0.05$).

**Conclusion:** The results of the study showed that TENS plus exercise treatment reduced pain severity and improved quality of life in patients with geriatric diabetic peripheral neuropathy, and promises hope for patients with diabetic neuropathic pain, which does not have a full therapy yet.

***Key Words*:** *Diabetic neuropathies, TENS, pain, exercise therapy, quality of life*

## Diyabetik Nöropatik Ağrılı Geriatrik Hastalarda TENS ve Egzersiz Tedavisinin Ağrı Şiddeti ve Yaşam Kalitesi Üzerine Etkileri: Retrospektif Çalışma

**Amaç:** Bu çalışmanın amacı, egzersiz tedavisine ek olarak uygulanan Transkütan Elektriksel Sinir Stimülasyonunun (TENS) diyabetik nöropatik ağrılı yaşlı bireylerin ağrı düzeyi ve yaşam kalitesi üzerine etkilerini geriye dönük olarak değerlendirmekti.

**Gereç ve Yöntem:** Altı haftalık fizyoterapi programını (TENS uygulaması; haftada 5 gün, günde 20 dakika ve kuvvetlendirme egzersizleri, germe egzersizleri, mat aktiviteleri, fonksiyonel aktiviteler ve normal eklem hareketleri gibi çeşitli egzersizler) tamamlayan, diyabetik nöropatik ağrısı olan yaşlı bireylere ait verilerin retrospektif olarak incelemesi yapıldı. Sonuç ölçümleri vücut diyagramı, Görsel Analog Skalası (VAS) ve Nottingham Sağlık Profili (NHP) idi.

**Bulgular:** Çalışmaya 16 hasta katıldı. Hastaların yaş ortancası 70 (65-83) idi. Hastaların ağrı düzeyleri incelendiğinde ortalama ağrı, şiddetli ağrı, hastaların en az ve mevcut ağrı düzeylerinin azaldığı gözlendi ($P<0.05$) ve NHP skorlarına göre ağrı, duygusal reaksiyonlar, uyku alt ölçekleri ve toplam NHP puanları tedaviden sonra anlamlı şekilde azaldı ($P<0.05$).

**Sonuç:** Çalışmanın sonuçları, TENS ile uygulanan egzersiz tedavisinin geriatrik diyabetik periferik nöropatili hastalarda ağrı şiddetini azalttığını ve yaşam kalitesini geliştirdiğini ve henüz tam bir tedavisi olmayan diyabetik nöropatik ağrılı hastalara umut verdiğini göstermiştir.

***Anahtar Kelimeler*:** *Diyabetik nöropatiler, TENS, ağrı, egzersiz tedavisi, yaşam kalitesi*

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## Introduction

Diabetes Mellitus is the most frequent reason for peripheral neuropathy especially in developing countries (1). Diabetic peripheral neuropathy is a complication of diabetes and is observed in about 30-50% of patients with diabetes and neuropathic pain is observed in about 11-20% of patients with diabetes (1, 2). Jensen et al. stated that the prevalence of neuropathic pain among patients with Diabetic peripheral neuropathy was 24.4% (3). In the Turkish Diabetic peripheral neuropathy population, neuropathic pain prevalence was 16% according to Erbas et al (1).

The medical treatment applied to patients with neuropathic pain is symptomatic. There is no medication whose efficiency is absolute for the moment. The target in medical treatment is not to eliminate the pain, but to take it to a bearable level (4, 5).

Neuro-stimulation treatment is used in an ever-growing frequency for patients with neuropathic pain in addition to medication or before the surgical treatment (6). TENS is used all over the world in pain treatment, and has received approval from the FDA in the USA, and is defined as applying electric current at a high frequency and a low amplitude

(below the pain threshold) to the painful area or to the nerve that stimulates that area via superficial electrodes (7, 8). It is considered that the influence occurs via the stimulation of big-scale afferent fibers which inhibits the activity of primary afferent pain neurons, or via a combination of endogenous opioid-dependent mechanisms that include the secretion of diamorphine, encephalin, and endorphins in the central nervous system. Different TENS applications aiming to decrease the pain may be applied in various combinations, frequencies, and densities (6, 9).

In the literature, there are changeable results on the long-term use of TENS, which is used by doctors, physiotherapists, and nurses in situations like acute and chronic pain (10). The TENS application, which is considered a safe and non-invasive method that decreases the pain especially in patients with mild chronic pain so it has been used widely in recent years in patients with Neuropathic pain (6, 11). On the other hand, there is limited literature about the effect of exercise on the pain level in patients with Diabetic Neuropathic pain. The benefits of exercise training generally have been tried to be explained by physiological mechanisms. These benefits of exercise training include improvements in nerve function, reductions in neuropathic pain, reductions in other types of sensory dysfunction (e.g., numbness) (2).

When the literature was examined it was observed that there were no studies in which geriatric individuals with diabetic neuropathic pain were examined or treated. Only one study in 2004 which was investigating the pain in geriatrics pointed out that 15.4% of elderly people were experienced burning in the past 2 weeks (12). Also, the negative effects of the Neuropathic pain on the quality of life of the elderly were neglected. European Federation of Neurologic Society stated in the compilation of the results of the studies on the effectiveness of the TENS application on patients with Neuropathic pains that it was not possible yet to suggest or to claim anything about the application in this patient group, however, it was also added that there was evidence at C level suggesting that high-frequency TENS application was more effective than placebo TENS (6, 13). The effectiveness of TENS was controversial in these studies and the results showed that TENS reduced or did not change the severity of pain. The aim of this study was to investigate the efficacy of TENS in older adults with diabetic neuropathic pain on the pain level and quality of life.

## Material and Methods

This study was conducted at the Hacettepe University. The University Ethics Committee approved the study (GO 17/622).

All older adults with diabetic neuropathic pain patients who were eligible and recruited to the physiotherapy program between September 2017 and June 2019 were considered for inclusion in this retrospective analysis. Identified data for the initial assessments and the final assessments (referred to as discharge) were extracted from medical records by a staff physical therapist. Because of the retrospective nature of the study, discharge data were only available for older adults with diabetic Neuropathic pain patients who completed the entire 30 exercise-sessions (Figure 1).

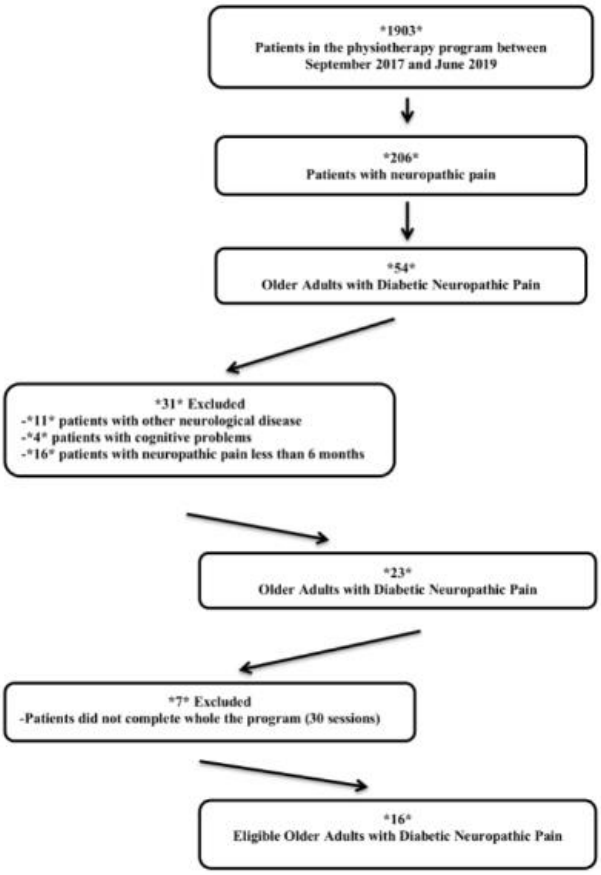


**Figure 1.** Flow diagram of the study

Patients entering the physiotherapy program had to be diagnosed as having Diabetic Neuropathic pain to join the program by a neurologist. Once the diagnosis was obtained, patients were scheduled for a physical therapy evaluation. Afterward, patients joined the program on a rolling basis and typically attended 5 sessions per week until they reached a total of 30 sessions. The minimum amount of time to complete the program was 6 weeks; however, if a patient missed a session because of illness, hospitalization, appointment, or other personal conflicts, the patient continued in the program until all 30 sessions were completed.

The information of the patients who met the inclusion and exclusion criteria were recorded from the patient files. Inclusion criteria were; having type 1 or 2 diabetes, having symptoms of neuropathic pain for at least 6 months, over 65 years of age, having pain that was resistant to medical treatments. Exclusion criteria were; having any other neurological disease (e.g. cerebrovascular ischemia), having cardiac arrhythmias or cardiac pacemakers, myocardial infarction within the

past 6 months, untreated hypertension, infection or gangrene, history of vascular insufficiency in the legs, drug or alcohol abuse, psychiatric disease, major organ disease, Patients taking medication that may influence neuropathic symptoms (such as α-lipoic acid, tricyclic antidepressants or anticonvulsants), and patients with ulcers, amputations caused by ischemia, or cancer diseases were excluded.

Extracted data comprised of the following data routinely collected in medical or PT records: The demographic characteristics, diagnoses, the date on which the pain started, and the accompanying complaints. Also, about Neuropathic pain, the neuropathic component and density of the pain were evaluated with the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain questionnaire, and the patients whose pain levels were 12 and over were included in the study, which is in accordance with the literature (14). The words that the patients used to describe the pain quality were recorded (burning, paresthesia, tingling, etc.). The other assessments were listed below;

**Characteristics of Pain (LANSS Pain Questionnaire):** This is a multi-dimensional scale used in discriminating the neuropathic and nociceptive pain from each other and is based on the analysis of the data from the questionnaire that can be applied while the patient is in a bed. The LANSS consists of 7 items, 5 of them questions pain symptoms. The other two are directed to sensory examination that includes allodynia and pin-prick test. Answers to these questions are as Yes/No. The scale was scored between 0-24, and the points above 12 made the physician consider the Neuropathic pain (14). The validity and reliability procedures of LANSS in Turkey were performed by Yücel in 2004 (15).

**Pain Localization (Body Diagram):** The patients were asked to mark the painful area on a body diagram. If there were more than one painful areas, these areas were marked with a different colored pen; however, the most painful area was taken into consideration in the treatment (16).

**Pain Severity (Visual Analog Scale):** The pain levels of the patients were evaluated using the Visual Analog Scale (VAS). The patients were asked to consider their pain levels for the past 2 weeks and mark the average, the most severe, the least severe, and current pain levels on a horizontal line (17).

**Health-Related Quality of Life (Nottingham Health Profile):** The Nottingham Health Profile (NHP) was used in evaluating the quality of life of the patients. This scale is a general quality of life scale that aims to measure the self-perceived health status in terms of physical, emotional, and social aspects (18). The NHP is also a general health questionnaire that has 6 sub-parameters under the headings, the Energy Level; pain; emotional reactions; social isolation; sleep; and physical activity; and which was answered as Yes/No. Each sub-parameter was between 0 and 100 points; the total points varied between 0-600 points (18). Its Turkish validity and reliability process was performed in 2000 by Ayşe Küçükdeveci and has used in patients with neuropathic pain (19).

**Intervention:** The patients who were included in the study received TENS application for 6 weeks, 5 days a week, 20 minutes a day in 30 sessions total. The application was performed with the Cefar Active XT TENS device which produces 2-channel, 4-sockets, asymmetric, biphasic square wave. In the application, the frequency of the square wave was set to 80 Hz beat width for each second; the beat width to 350μs, and the current amplitude was set to 0-100 mA. The electrodes of the device (dura-stick plus 5*5 cm. cable, smooth needle pin sticky electrode) were set to face the upper part of the painful area. The current amplitude was kept at a level that would not cause/increase pain in the patient by considering the sensory threshold of the patient.

Strengthening (trunk flexion-extension) and stretching exercises (stretching and elongation), mat activities (bridging), functional activities (weight transfer from anterior to posterior and left to right), and range of motion exercises (trunk flexion, extension, left-right rotation, lateral flexion) were performed by the patients. The exercises were applied carefully not to cause pain and tiredness in patients.

Average pain severity was used for calculating sample size. The effect size was described with post hoc analysis as 0.87 by using means, standard deviations. The power of the study was calculated from the Gpower 3.0.10 analysis program and was found 88% for 16 individuals.

**Statistical Analysis:** The statistical analyses of the study were made by using the SPSS 15.00 Statistical Package Program. The variables which were defined by measurements were expressed as median (25-75% interquartile range (IQR)), and percentage (%) was used for the variables that were defined by counting. The statistics of the changes between the pre-treatment and post-treatment values within and outside the groups and the areas were evaluated by using the 'Wilcoxon test'.

## Results

Eleven men/5 women, 16 patients in total participated in the study. The median age of the patients was 70 (65-83) years. The demographic characteristics of the patients were given in Table 1.

Seven of the patients stated that they had pain in their feet, 4 of them in ankles, 4 in their hands, and 1 in their knees and, marked these areas in the body diagram. Words used by the patients while they were telling the history of their pains were considered, it became obvious that 11 patients used the word 'paresthesia'; 11 patients used the word 'tingling'; 12 patients used the word 'burning'; 9 patients used the word 'stinging'; 4 patients used the word 'electric shock'. Also, 8 patients told that the pain lessened while they were relaxing, one patient told that the pain lessened

while sleeping, 2 patients told that the lessening was during watching television, and 5 patients told that the pain was never relieved in any way. Besides, 8 patients added that their pains increased when they had an activity, and 2 patients told that their pains increased when they were angry. It was observed that the LANSS scores of the patients were between minimum 13 and maximum of 24 points (Table 1).

**Table 1.** Demographics of patients

| N=16 | Median (IQR) |
|---|---|
| Age (year) | 70 (67-74) |
| Height (cm) | 169.50 (165-179.5) |
| Weight (kg) | 76.50 (63.75-80) |
| Duration of pain (month) | 22 (12-45) |
| LANSS scores | 15 (14-18.5) |

LANSS: Leeds assessment of neuropathic symptoms and signs

**Table 2**. Pre and post treatment visual analog scale results of patients

| Pain severity | Pre-treatment Median (IQR) | Post-treatment Median (IQR) | P |
|---|---|---|---|
| Average | 7.25 (5-8) | 5 (4-7) | 0.004* |
| Severe | 9.50 (8-10) | 6 (5-7.75) | 0.001* |
| Least severe | 4 (0.5-5) | 0 (0-3.5) | 0.001* |
| Current | 5.50 (4-8) | 3 (2-6.5) | 0.016* |

Wilcoxon test, *P<0.05

**Table 3**. Pre-treatment and post-tratment quality of life scores of patients

| Nottingham Health profile | Pre-treatment Median (IQR) | Post-treatment Median (IQR) | P |
|---|---|---|---|
| Energy level | 60.80 (60.80-100) | 60.80 (27.20-90.80) | 0.100 |
| Pain | 76.36 (41.93-89.89) | 30.54 (13.22-60.57) | 0.001* |
| Emotional reactions | 34.74 (25.52-57.31) | 24.39 (9.42-41.36) | 0.008* |
| Social isolation | 22.27 (0-41.62) | 22.37 (0-37.61) | 0.656 |
| Sleep | 36.72 (15.02-64.18) | 21.07 (0-44.07) | 0.001* |
| Physical activity | 53.93 (34.31-76.06) | 60.28 (25.63-68.13) | 0.282 |
| Total | 284.86 (245.01-336.19) | 238.85 (105.24-317.13) | 0.002* |

Wilcoxon test, *P<0.05

When the pain levels of the patients were examined by VAS, it was observed that the average, severe, the least severe, and current pain levels of the patients decreased statistically meaningful after the TENS plus exercise treatment (P<0.05). The pre-post treatment pain results of the patients were given in Table 2.

When the NHP scores were examined it was observed that the pain after the treatment, emotional reactions, sleep, and total NHP points decreased meaningfully (P<0.05). It was also observed that there were no meaningful differences in the energy level, social isolation, and physical activity points (P>0.05). The pre-post treatment results of the patients are given in Table 3.

## Discussion

This study was a retrospective analysis of outcomes measures collected in diabetic patients who had enrolled and completed the physiotherapy program for Neuropathic pain. The most important result of the present study was the reduction of pain severity and increased quality of life of older adults with Diabetic Neuropathic pain. These results promise that TENS plus exercise treatment can be helpful in the rehabilitation of neuropathic pain.

Neuropathic pain, which is considered as lifelong prevalence is as high as 10%, is one of the pain syndromes that is the most difficult to cure (20). The European Federation of Neurologic Society stated in the guideline on neuropathic pain treatments ‘The number of the studies on the issue is increasing; however, the neuropathic pain treatment is not yet satisfactory’ (4). When the studies on the application of TENS in neuropathic pain treatment were searched in the literature, it was observed that the studies were mainly on patients with general neuropathic pain, or patients with spinal cord injuries (21). In this concept, the present study is the first one in which applied to the patients with geriatric diabetic neuropathic pain and includes the quality of life results. Moreover, this is the first study in which TENS was added to exercise in neuropathic pain patients.

There are very few studies in the literature on the efficiency of the neuro-stimulation treatments applied to patients with diabetic neuropathic pain. Somers’ conducted a study in 1999 on a patient with diabetic neuropathy and applied TENS on the lumbar area for 20 minutes a day and for 17 sessions, and reported that pains, which were 9 in the left hip; 9 in the left knee, and 4 in the ankle at the beginning according to VAS, all disappeared after the treatment (11). The researchers suggested that 2 mechanisms played a role in eliminating the pain with TENS. The first one was based on the assumption that TENS may block directly the abnormal spontaneous activity in the small-scale peripheral nerves that have the duty of transferring the pain. In this assumption, it was considered that TENS affected the nociceptive transfer which was located on the back horn of the spinal cord (11). According to the 2$^{nd}$ mechanism, the stimulation should be applied to the spinal nerve segment that innerves the painful area. Since the researchers performed the application in the

lumbar area, and since they found relief in the knees, this mechanism's being effective was a far possibility and the relief was due to the first mechanism (11). In the present study, similar to the study conducted by Somers &Somers, after the TENS application the average, the most severe, the least severe pain, and the current pain levels decreased meaningfully. Another study on the effectiveness of the neuro-stimulation treatment performed on patients with diabetic neuropathic pain was conducted by Bosi et al. (22). The researchers applied electromagnetic stimulation to 31 patients with diabetic neuropathic pain and reported that the application led to meaningful relief in the daytime and night-time pain levels. The results of this study are in accordance with the study conducted by Bosi et al. (22).

Neuropathic pain negative affects quality of life not only because of the pain but also due to the depression-related to the pain, sleep disorders, and loss in working capacity. Rosberg, Ciaramitaro, Gustorf, and McCarberg conducted studies on patients with neuropathic pain and compared them with healthy peers, and reported that their quality of life levels were lower in all parameters (18, 23-25). The study of McCarberg reported that although there were decreases in all parameters of the quality of life in the patients with neuropathic pain, especially social functions, mental health, physical functions, and body pain affect the quality of life mostly (25). Although there was no healthy control group in the present study, the findings show that the quality of life of the patients was affected negatively, as in the literature, and especially the parameters pain, energy level, and physical activity decreased the level of the quality of life. The reasons for the difference of the present study with the other studies in the literature in terms of quality of life sub-parameters from the fact that this study has been conducted with geriatric individuals. It is a well-known fact that the energy level and physical activity levels decrease in geriatric individuals. There are no studies conducted in the literature on the treatment methods on the quality of life of the geriatric diabetic neuropathic pain patients. In this sense, the present study is the first one in the literature in this field. One of the most important results of this study was the improvement in the quality of life of the patients after the TENS plus exercise treatment. We consider that the improvements in pain, emotional reactions, and sleep parameters of the patients are very important for the elderly individuals.

When the literature was examined, no studies were found about the effect of exercise on the pain level in patients with diabetic neuropathic pain. Only one study was found on this subject which was conducted by Ulger O. et al. (26), the results of the exercise treatment applied to patients with phantom pain. In the study, it was shared that the *stump exercises* decreased the pain level in 20 patients who were traumatically amputated. In the present study, the decrease in the pain levels after the exercises and TENS treatment was in accordance with the results of the study conducted by Ulger et al. (26). Dobson et al.(2) stated in their review article that there was a need for researches that investigate the exercise-induced benefits in neuropathic pain.

The most important limitation of the study is that there were no control groups. However, the fact that the superiority of TENS over Sham TENS has been stated in the compilation of EFNS, did not abolish the limitations of our study. Another important limitation is that TENS and exercise treatment were applied together in the study. Therefore, there is no information about which application was effective or more effective than the other one. Detailed studies are needed for more isolated and clear results.

In geriatric patients, pain is one of the most important negative factors that affect the quality of life. When disorders like paresthesia, burning, tingling are considered, it is commented that the neuropathic pain is more distressing than any other painful situations. The results of the present study promise hope to increase the quality of life in patients with geriatric diabetic neuropathic pain patients with TENS plus exercise treatment. Randomized controlled future studies with proven results will have positive effects on the quality of life of the patients with geriatric diabetic neuropathic pain which has reached an important level in the whole population.

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