

To Find the Effect of TENS on Painful Type-II Diabetic Peripheral Neuropathy using NTSS-6 Questionnaire

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Abstract: Background: Peripheral neuropathy is the most common complication of type-II DM, affecting nearly one of every three patients of it and increasing in incidence with the duration of diabetes. Painful Diabetic Neuropathy (PDN) is the clinical scenario of neuropathic pain arising as a direct consequence of abnormalities in the peripheral somatosensory system. Pain tends to be bilateral and predominantly involves lower limbs in stocking distribution. NTSS-6 Questionnaire evaluates the frequency and intensity of individual neuropathy sensory symptoms in patients with DPN. Objective: To examine the efficacy of TENS on NTSS-6 score in patients with type-II DPN. Method: 30 patients fulfilling the selection criteria were equally divided into two groups. Group A (experimental) was given High frequency, sensory intensity TENS. Group B (control) was given sham TENS. Pain frequency & intensity of different sensory symptoms were recorded using NTSS-6 Questionnaire before and after 4 weeks of intervention. Result: For within group analysis Wilcoxon signed rank test and for between group analyses Mann-Whitney U test was used. Statistical analysis showed significant improvement in sensory symptoms after 4weeks. Conclusion: It can be concluded that as a non-invasive treatment, TENS therapy is a safe complementary approach in treatment of patients with symptomatic DPN.

Keywords: Type-II Diabetes Mellitus (DM), Diabetic Peripheral Neuropathy (DPN), Transcutaneous Electrical Nerve Stimulation (TENS), Neuropathy Total Symptom Score-6 Questionnaire (NTSS-6).

1. Introduction

The most common form of diabetic neuropathy is the “Distal Sensorimotor Poly-Neuropathy (DSPN)”.^[1] Diabetic Peripheral Neuropathy (DPN) is defined as a symmetrical, length dependant distal sensory-motor polyneuropathy attributable to metabolic and microvascular alterations.^[2] Peripheral neuropathy is the most common complication of type-II DM, affecting nearly one of every three patients with type-II DM and increasing in incidence with the duration of diabetes.^[3] DPN accounts for 12.3% at original diagnosis of diabetes and 30-50% after 12 years history of diabetes.^[4]

A common phenotype of DPN is **Painful Diabetic Neuropathy (PDN)**. PDN is the clinical scenario of neuropathic pain arising as a direct consequence of abnormalities in the peripheral somatosensory system in the people with DPN.^[2] Pain tends to be bilateral and predominantly involves lower limbs, specifically the foot, which extends to involve the feet and legs in a stocking distribution. This distribution pattern occurs because the longest sensory axons are usually the first to be affected by diabetes.^{[1], [5]} A hallmark of PDN is that, this pain usually not exacerbated by walking but rather is worse at night when the patient is off their feet and their feet are elevated. Patients typically describe their neuropathic pain by using the words such as, “hot”, “burning”, “electric”, “jolts”, “sharp”, “tingling” and “pins and needles”. It may also be accompanied by allodynia and hyperalgesia.^[1] The prevalence of PDN is about 20% in patients with type-II DM and it affects from 16-33% of people with diabetes.^{[2], [6]}

A cross-sectional study showed that, patients with PDN have significantly poorer quality of life compared to those without

neuropathy and those with non-neuropathic pain. The severity of PDN is associated with anxiety and depression, as well as significant sleep impairment.^[1]

Transcutaneous Electrical Nerve Stimulation (TENS) selectively activate large diameter A_β fibres without activating smaller diameter nociceptive fibres (A_δ & C). This will produce pain relief (pain-gate theory). It has few side-effects compared to drug adverse reactions and is cheap when compared with long-term drug therapy.^{[7], [8]}

The **Neuropathy Total Symptom Score-6 (NTSS-6)** questionnaire was developed to evaluate the frequency and intensity of individual neuropathy sensory symptoms identified frequently by patients with DPN i.e. numbness and/or insensitivity; prickling and/or tingling sensation; burning sensation; aching pain and/or tightness; sharp, shooting, lancinating pain; and allodynia and/or hyperalgesia. The NTSS-6 evaluates the most prominent sensory symptoms of DPN in a simple, reliable, multidimensional, and minimally burdensome manner for symptomatic DPN patients. The NTSS-6 incorporates a frequency dimension, in addition to the standard intensity dimension, for evaluating each individual symptom.^[9]

Except tight glucose control, treatments for PDN are for symptomatic relief that is reducing pain and other sensory symptoms. Many pharmacologic drugs have been suggested for symptomatic relief but, they have potential side-effects. There are very few studies which show effect of TENS on different sensory symptoms of PDN. Hence, the need of this study is to explore the beneficial effects of TENS for painful type-II diabetic peripheral neuropathy using NTSS-6 Questionnaire.

2. Materials and Method

Study Setting: Physiotherapy department of General Hospital.

Study Design: Interventional Study

Sampling Technique: Convenience Sampling

Sample Size: 30 Subjects

Experimental Group (Group A): 15 Subjects

Control Group (Group B): 15 Subjects

Selection Criteria

- **Inclusion Criteria:** Both male and female participants between 50-70 years of age with documented type-II diabetes and with symptoms of painful peripheral neuropathy involving both lower limbs for more than 3 weeks. DPN confirmed with NCV study.
- **Exclusion Criteria:** Other type of neuropathy or radicular pain, or other musculoskeletal pain which hampers the patient's participation in the study. Patients with severe medical condition within past six months. Patients having clinical evidence of vascular insufficiency of legs or feet. Psychiatric disease or substance abuse including alcohol. Total loss of sensation. Patients on corticosteroid or chemotherapeutic agents.

Outcome Measure:

Neuropathy Total Symptom Score-6 (NTSS-6) Questionnaire: It measures intensity and frequency of six symptoms:

- Aching Pain
- Allodynia
- Burning Pain
- Lancinating Pain
- Numbness
- Prickling Sensation

Patient was asked about the symptoms felt by him or her. Frequency and Intensity of each symptom graded by the therapist according to the definitions provided in the questionnaire. After evaluating all symptoms, total score was made by sum of score.^[9]

3. Materials



4. Procedure

30 patients fulfilling the selection criteria were evaluated according to the assessment form. Frequency and intensity of different sensory symptoms of Diabetic Neuropathy were

recorded using NTSS-6 Questionnaire. The patients were randomly divided into two groups.

Group A: Experimental group (15 patients)

Group B: Control group (15 patients)

Group A was given High frequency, Sensory intensity TENS and Group B was given Sham TENS.

Parameters:

Frequency: 80 to 100Hz

Pulse Width: 100 to 200µs

Mode: Continuous

Intensity: Gradually increased to the patient's comfortable level (there should not be muscle contraction)

Placement of electrodes:

- First pair of electrode: Para-spinal at the lower lumbar region (spinal dermatome level)
- Second pair of electrode: Ventral and dorsal aspect of the foot (over the painful area)

Position of patient: Side lying (or patient's comfortable position)

Time: 15 minutes for each leg (total 30 minutes)

Total duration of treatment: 5 days a week for 4 weeks

Statistical Analysis

The data analysis was done using the statistical software SPSS-16. Before applying statistical tests, data was screened for normal distribution. Confidence interval was set at 95% and $p < 0.05$ was considered as significant. For within the group analysis, Wilcoxon Signed Rank Test was used. For comparison of outcome measure in between two groups, Mann-Whitney U Test was used.

5. Result

Table 1: Age distribution

Group	No. of Patients	Mean	±SD
Group-A	15	62	5.251
Group-B	15	64.13	7.586

Table 2: Difference in means of NTSS-6 score values

Group	Before	After	Z value	P value
Group-A	5.793 (15 patients)	2.050 (13 patients)	-3.186	0.001
Group-B	5.283 (15 patients)	3.717 (12 patients)	-2.848	0.04

Table 3: Analysis of NTSS-6 score in between two groups

Group	Mean of difference	Number of patients	±SD	U value	P value
Group-A	3.916	13	0.782	13	0.000
Group-B	1.638	12	1.380		

6. Discussion

The purpose of the present study was to find the effects of TENS in reducing different sensory symptoms of painful type-II Diabetic Peripheral Neuropathy. 30 subjects were equally divided into experimental group (Group-A) and control group (Group-B). Group A had received treatment with active TENS and Group-B had received treatment with sham TENS. Both the experimental and control group were

similar at the baseline characteristics of age and NTSS-6 score.

The results of within group analysis of the present study showed that there was reduction in the mean NTSS-6 score from 5.79 ± 1.32 to 2.05 ± 0.82 in experimental group, suggesting a significant reduction in sensory symptoms ($p=0.001$). But in control group, there was reduction in mean NTSS-6 score from 5.28 ± 2.29 to 3.72 ± 1.29 , suggesting some reduction in sensory symptoms ($p=0.04$) but they are not significant.

According to the study done by **Dinesh Kumar and Howard J. Marshall (1997)** on "Diabetic peripheral neuropathy: Amelioration of pain with TENS", the natural course of neuropathic symptoms is highly variable and caution must be taken in interpreting the outcome of a short-term treatment modality. To control this difficulty to some extent, we should have a parallel group of sham treated group.^[10]

The result of between group analyses of the present study showed there was highly significant reduction in sensory symptoms ($p=0.000$) of subjects in experimental group compared to control group.

According to **David L Somers and Martha F Somers (1999)**, there are two potential mechanisms by which high frequency TENS can relieve the pain of diabetic neuropathy. It is possible that TENS alleviates pain by directly blocking abnormal spontaneous activity in small-diameter, pain mediating peripheral nerves. This mechanism requires electrical stimulation to be applied directly to the spontaneously active nerve. TENS can also relieve pain of diabetic neuropathy by altering nociceptive transmission in the dorsal cord of spinal cord and this requires the stimulation be delivered to spinal cord segments that innervate the painful area. Both of these mechanisms can be responsible for pain relieve in this study.^[11]

L.S. Chesterton et al. conducted a RCT, which evaluated the effects of varying frequency, intensity and stimulation site, of TENS in an experimental model of pain, indicated that only TENS with high frequency and high intensity achieved significantly clinical hypoalgesic effects.^[12]

Julka et al.'s study, which observed the effect of TENS therapy on 82 diabetic patients with neuropathic symptoms, has demonstrated that TENS therapy provided continuous advantage in neuropathic symptoms for average 1.7 years. It means that TENS therapy may have long term effect on neuropathic symptoms.^[13]

Thus, high frequency and sensory intensity TENS can be added in the treatment plan of patients with neuropathic pain in diabetics to relieve pain and discomfort without any systemic and local side effects.

7. Future Recommendation

- 1) A large sample size study should be done to make the findings more specific and applicable to whole population.

- 2) Study can be done in neuropathic patients in both type-I and type-II DM patients and comparison can be done between them.
- 3) Specific follow up periods should be set to find the carryover effect of the TENS.
- 4) Effect of TENS can be compared or its additive effect with other treatment i.e. exercise, drug therapy, glycaemic control can be seen.

8. Conclusion

Result shows that, Transcutaneous Electrical Nerve Stimulation in the form of high frequency, sensory intensity (80-100Hz frequency and 100-200 μ s pulse duration) for 4 weeks has beneficial effects on sensory symptoms of painful type-II Diabetic Peripheral Neuropathy. TENS was well tolerated and no treatment related adverse events registered in TENS group. So, it can be concluded that, as a non-invasive treatment, TENS therapy is a safe complementary approach in treatment of patients with symptomatic diabetic peripheral neuropathy.

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