"A comparative study between effectiveness of external electrical muscle stimulation versus TENS in the Management of Diabetic Peripheral Neuropathy"

A Dissertation Submitted In Partial Fulfillment

of the Requirements for the Degree of

MASTER OF PHYSIOTHERAPY

With Specialization In

ADVANCED PHYSIOTHERAPY IN NEUROLOGY

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Submitted to

THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY
Chennai

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION

COLLEGE OF PHYSIOTHERAPY

Department Of Post Graduate Studies

Komarapalayam - 638 183

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CERTIFICATE

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

INTRODUCTION

Diabetes is severe disease affecting over hundred millions of people endure from diabetes with in the world. In USA about 16 million people are affected from diabetes.

It affects all age group from children to elderly individual by type II Diabetes have greater damage of nerve ,kidney, eye and coronary heart diseases.

Diabetes believed to be the national IV leading for death. In the nervous system could also be disturbed or damaged causing severe pain, loss of felling this situation is referred to neuropathy

Diabetic neuropathy is a complication caused by diabetes symptoms includes numbness and some time pain in the hand, feet or in legs

Peripheral neuropathy is a problem with the nerve that carry information to and from the brain and spinal cord this produce pain loss of sensation and in ability to control muscle.

Peripheral means away from the center of the body distance from spinal cord, ‘neuro” means nerve, ‘pathy’ means abnormal about 60 to 70% of diabetic patient have mild to severe form of nervous system damage which leads to diabetic poly neuropathy.

Peripheral nerves, called sensory nerves,sents messages (stimuli) to the brain and spinal cord, so we can feel certain sensations. For example, when we prick our finger, sensory nerves transmit this information to the brain and we will feel a sharp sensation. Someone with sensory nerve damage may feel numbness rather than pain.

Prevalence - the projected 18 millions of people increases in the number of cases of diabetes in 2050, 37% are due to changes in demographic composition, 27% are due to population growth, and 36% are due to increasing rates.

Diabetic neuropathy is classified as peripheral, autonomic proximal (or) focal, peripheral neuropathy is the most common type of diabetic neuropathy and also called as distal symmetric neuropathy or sensorimotor neuropathy. Peripheral neuropathy affects nerves of toes, feet, legs, hands & arms. Feet & legs are likely to be affected before hands and arms.

The first treatment is to bring sensation back by bringing the blood sugar level with in the normal range to prevent further nerve damage. Diabetic peripheral neuropathy is treated with medication and physiotherapy treatment modality like TENS, external electrical muscle stimulation and exercises.

This study was carried out to determine the effectiveness of External Electrical Muscle Stimulator and Transcutaneous electrical nerve stimulation (TENS)in Management of Diabetic Peripheral Neuropathy using Neuropathy Total Symptom Score-6 (NTSS-6) and LEFS.

AIMS AND OBJECTIVES

AIM OF THE STUDY

To compare the effectiveness of External Electrical Muscle Stimulator and Transcutaneous electrical nerve stimulation in Management of Diabetic Peripheral Neuropathy.

OBJECTIVES OF THE STUDY

- To determine the effectiveness of External Electrical Muscle Stimulator in Diabetic Peripheral Neuropathy.
- To determine the effectiveness of transcutaneous electrical nerve stimulation in Diabetic Peripheral Neuropathy.
- To compare the effects of External Electrical Muscle Stimulator and Transcutaneous electrical nerve stimulation in Management of Diabetic Peripheral Neuropathy in sensory reeducation.
- To compare the effects of External Electrical Muscle Stimulator and Transcutaneous electrical nerve stimulation in Management of Diabetic Peripheral Neuropathy using lower extremity functional scale.
- To find out the effective treatment regarding pain, functional status, and sensation in Diabetic Peripheral Neuropathy.

HYPOTHESIS

NULL HYPOTHESIS

The null hypothesis states that there was no significant difference between External Electrical Muscle Stimulation Versus Transcutaneous electrical nerve stimulation in the Management of Diabetic Peripheral Neuropathy.

ALTERNATE HYPOTHESIS

The alternate hypothesis states that there was significant difference between External Electrical Muscle Stimulation Versus Transcutaneous electrical nerve stimulation in the Management of Diabetic Peripheral Neuropathy.

REVIEW OF LITERATURE

- **L.Reichstein et. al.,(Apr 2005)**

The aim of the study was to find out the effectiveness of high frequency external muscle stimulation versus TENS on symptomatic diabetic neuropathy .41 patient who is suffering from diabetes in which 20 patients with out pain and 21 patients with pain duration of treatment 30 min daily for 3 consecutive days for both lower extremities .The parameter used are HbA1c (mmol/l) and Neurological impairment scale. The result of the study say that high frequency external muscle stimulation can ameliorate the discomfort pain, reduction in HbA1c,improvement in Neurological impairment scale associated with diabetic peripheral neuropathy than TENS.

The conclusion of the study shows that external muscle stimulation is more effective than TENS for diabetic sensory polyneuropathy.

- **Per M.Humpert MD et al (Jan 2009)**

The aim of the study to find out the effect of external muscle stimulation in improving burning sensation and sleeping disturbance in patient with type 2 diabetes with symptomatic neuropathy. About 92 patients with type 2 diabetes with neuropathy symptomatic are taken for study. Patient treated with EMS twice a week for 4 weeks. The parameter used numerical scale.

The result of the study shows that about 73% of patients is marked improvement in numerical scale of symptoms such as pain, burning sensation, numbness, sleeping disturbance and paresthesia.

The Study concluded that external muscle stimulation is an effective treatment for symptomatic neuropathy patient with type 2 diabetes.

- **Peter EJ et al (oct.1998)**

The purpose of the study was to evaluate electrical stimulation on vascular perfusion in diabetic patients. About 19 patients were selected based on transcutaneous oximeter. The parameter used is Transcutaneous oximeter values of which vascular perfusion was measured before and after external muscle stimulation for a period of two days.

The study result shows that external muscle stimulation induces transient rise in skin perfusion in patient with diabetes.

The study concluded that external muscle stimulation is an effective treatment for symptomatic neuropathy patient with type 2 diabetes.

- **MD Edward et al (oct. 2005)**

The study was conducted to find out the development and validity testing of the neuropathy total symptom score-6 (NTSS-6) questionnaires for

the study of sensory symptoms of diabetic poly neuropathy. About 205 patients where used in 10 centers in USA.

The study concluded that neuropathy total symptom score-6 was valid assessment of neuropathy sensory symptoms of patients with diabetes and diabetic polyneuropathy. It is more reliable and valid to evaluate diabetic polyneuropathy in this well defined world.

- **Moharic et al (Sep. 2010)**

Aim of the study was conducted to determine the effectiveness of TENS in painful neuropathy condition. About 46 patients was treated with tens for 3 consecutive hours for 3 weeks. Treatment effect was evaluated by cold, warm ,cold pain threshold ,heat pain threshold, vibration perception threshold and touch perception threshold.

The result concluded that there is no statistically significant changes in cold, warm ,cold pain threshold ,heat pain threshold, vibration perception threshold and touch perception threshold. It does not alter C fibers, A (delta), nor A (beta) fibers mediated perception threshold.

Study concluded that TENS does not alter above fibers mediated perception threshold in diabetic peripheral neuropathy.

- **Rose b et. al.,(2006)**

The aim of the study was to evaluate the beneficial effect of external muscle stimulation on glycaemic control in patient with type 2 diabetes .In this study 16 patients on antihyperglycemic drug 6weeks of High frequency external muscle stimulation. The parameter's used are HbA1c, blood samples where drawn.

The result of study shows that there is a reduction of blood sugar level, body weight and HbA1c (-0.4%) in the patient with type2 diabetes.

The study concludes that EMS is an additional treatment option for patients with type two diabetes who can not perform physical activity.

- **E Hultman and LL Spriet (may. 1985)**

The study was conducted to evaluate the skeletal muscle metabolism, contraction force and glycogen utilization during prolonged electrical stimulation in human quadriceps muscles of 7 volunteer's duration of 45 min of electrical stimulation titanic trains at 20Hz lasting 1.6s separated by 1.6s pause. Muscle biopsies where taken at rest and during stimulation that reduces blood glucose level in diabetic patients. The parameter used is muscle biopsies during rest and during stimulation.

The study result conclude that external stimulation increases the skeletal muscle metabolism

- **M Lankisch et al**

The aim of the study was to determine the new possibilities of treatment for type 2 diabetes by means of external muscle stimulation. It's a 12 week in these 2 weeks of external muscle stimulation. The electrode is placed over the thigh and shunk .The GLUT 1 and GLUT 4, body weight and HbA1c used as parameters .

The study result states that there is body mass index and HbA1c is reduced and increase in GLUT 1 and GLUT 4.

The study concluded that external muscle stimulation is clinically relevant to patients with type 2 diabetes could be demonstrated.

- **Deephika Sharma et al (Oct 2010)**

The study was to evaluate the effect of external muscle stimulation on blood sugar level and lipid profile of sedentary type 2 diabetes patients. About 20 patients under gone electrical stimulation over quadriceps muscles 40 min/day/3 days/ week for continuous 2 weeks . Parameter blood test was taken on 1st and last day of treatment.

The study result concludes that blood sugar level is reduced by means of external muscle stimulation in type 2 diabetic patients.

The study concluded that external muscle stimulation is clinically relevant to patients with type 2 diabetes could be demonstrated

- **Jill M Binkley et al (Jan. 1999)**

The purpose of this study was to assess the reliability, construct validity, and sensitivity to change of the Lower Extremity Functional Scale. About 107 patients with lower-extremity dysfunction .

The study result states that Lower Extremity Functional Scale was excellent.

Conclusion and Discussion **.** The Lower Extremity Functional Scale is reliable, and construct validity was supported by comparison with the SF-36. The sensitivity to change of the Lower Extremity Functional Scale was superior to that of the SF-36 in this population. The Lower Extremity Functional Scale is efficient to administer and score and is applicable for research purposes and clinical decision making for individual patients.

- **MD Edward J Bastyr III 12(July 2005)**

The aim of this study was to develop and validate a neuropathy sensory symptom scale, the Neuropathy Total Symptom Score-6 (NTSS-6), which evaluates individual neuropathy sensory symptoms in patients with diabetes mellitus (DM) and diabetic peripheral neuropathy (DPN) in clinical trials.

The parameter's used are 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 study result conclude that the Neuropathy Total Symptom Score-6 (NTSS-6)provided a valid assessment of neuropathy sensory symptoms in this sample of patients with diabetes mellitus and diabetic peripheral neuropathy, which suggests that it may be useful for symptom evaluation in clinical trials and practice. The Neuropathy Total Symptom Score-6 (NTSS-6) showed internal consistency, test-retest reliability, and construct validity.

MATERIALS AND METHDOLOGY

MATERIALS

- Couch.
- Pillows.
- External Electrical Muscle Stimulator.
- Transcutaneous Electrical Muscle Stimulator(TENS)
- Electrode gel.
- Strap.
- Cotton.
- Lower extremity functional scale and Neuropathy Total Symptom Score-6 chart.

METHODOLOGY

Study Design

Quasi Experimental Study Design.

Study Setting

The study was conducted at out patient department in J.K.K. Munirajahh Medical Research Foundation College of Physiotherapy, Komarapalayam under the supervision of the higher concerns.

Sampling Method

Convenient sampling method.

Sample Size

Thirty patients with diabetic peripheral neuropathy, who comes under the inclusion criteria, were taken for the study.

Study Duration

The study was conducted for a course of 6 months, and treatment duration for each patient was 20 min per sitting, 4 sittings per week for one month.

Inclusion Criteria

- Age group –50 years and above.
- Sex – both sexes.
- Diabetic peripheral neuropathy.
- HbA1(C) <8.
- Neuropathy Disability Score (NDS) <6

Exclusion Criteria

- Pregnancy.
- Malignancy.
- vessel involvement.
- Patient with cardiac pacemaker.
- Infective skin lesion
- Varicose vein.
- Presence of ulcer.
- Insulin dependent diabetes mellitus.
- HbA1(C)>8.
- Amputation

Parameters

- Neuropathy Total Symptom Score-6 (NTSS-6)
- Lower Extremity Functional Scale.

Procedure

A total number of 30 patients having Diabetic peripheral neuropathy who met the inclusion criteria were recruited by convenient sampling method. After the informed consent obtained, they were partitioned into two groups as Group A and Group B, with 15 patients in each.

Hence prior to the onset of treatment, pre-tests were conducted using Neuropathy Total Symptom Score-6 and Lower Extremity Functional Scale and results were recorded for both groups.

Statistical Tools

Paired‘t’ test:

The paired‘t’ test was used to find out the statistical significance between pre and post test of patients treated with external electrical muscle stimulation and TENS.

Formula: Paired‘t’ test:

$$s = \sqrt{\frac{\sum d^2 - \frac{(\sum d)^2}{n}}{n-1}}$$

$$t = \frac{\bar{d}\sqrt{n}}{s}$$

d = difference between pre test Vs post test values

$\bar{d}$ = mean difference

n = total number of subjects

s = standard deviation.

Unpaired‘t’ test:

The unpaired‘t’ test was used to compare the statistically significant difference between Group A and Group B.

Formula: Unpaired‘t’ test:

$$s = \sqrt{\frac{(n_1 - 1)s_1^{\,2} + (n_2 - 1)s_2^{\,2}}{n_1 + n_2 - 2}}$$

$$t = \frac{\left|\bar{x}_1 - \bar{x}_2\right|}{s\sqrt{{}^{1}/_{n_1} + {}^{1}/_{n_2}}}$$

n_1 = total number of subjects in group A

n_2 = total number of subjects in group B

x_1 = difference between pre test Vs post test of group A

$\bar{x}_1$ = mean difference between pre test Vs post test of Group A

x_2 = difference between pretest Vs post test of group B

$\bar{x}_2$ = mean difference between pre test Vs post test of Group B

s = standard deviation.

DATA PRESENTATION

TABLE I

S.No	Group A Transcutaneous electrical nerve stimulation				Group B External Electrical Muscle Stimulator			
	Neuropathy Total Symptom Score-6 (NTSS-6)		Lower Extremity Functional Scale (LEFS)		Neuropathy Total Symptom Score-6 (NTSS-6)		Lower Extremity Functional Scale(LEFS)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1.	12	7	35	55	10	2	39	75
2.	11	6	36	51	11	3	37	71
3.	12	5	38	52	12	2	38	70
4.	10	6	37	55	12	3	35	69
5.	11	6	40	59	10	2	41	68
6.	9	5	41	57	11	3	40	74
7.	10	6	42	60	9	2	42	72
8.	11	6	43	58	9	2	44	69
9.	11	6	37	50	11	2	45	73
10.	12	8	36	49	10	2	43	70
11.	11	7	40	61	12	3	35	74
12.	10	6	41	60	11	3	36	75
13.	10	5	35	51	11	3	37	68
14.	11	6	36	50	9	2	39	69
15.	12	7	44	60	8	2	38	71

DATA ANALYSIS AND INTERPRETATION.

This section deals with the analysis and interpretation of data collected from group A and Group B who underwent Transcutaneous electrical nerve stimulation and External electrical muscle stimulator

TABLE – II

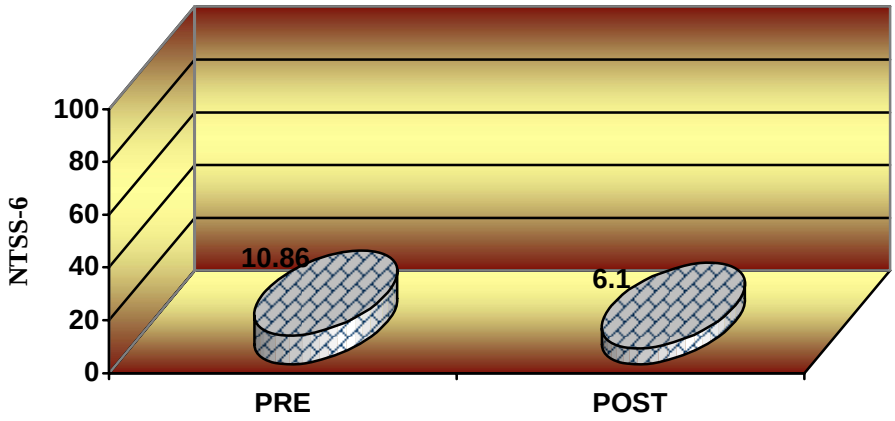
Group – A

Table II represents the mean values, mean difference, standard deviation, and paired 't' value between pre test Vs post test values of Patient Rated diabetic peripheral neuropathy for group A who have been subjected to Transcutaneous electrical nerve stimulation.

NTSS-6	Mean	Mean difference	Standard deviation	Paired 't' value
Pre test	10.86	4.76	0.79	23.02
Post test	6.1			

It shows the analysis of Patient Rated Diabetic Peripheral Neuropathy; the paired 't' value of pre Vs post sessions of group A was 23.02 at 0.05 level of significance, which was greater than the tabulated value of 2.15. This showed that there was a statistical significant difference in between pre Vs post test results. The pre test mean was 10.86, the post test mean was 6.1 and mean difference was 4.76, which showed that there was a decrease in Patient Rated Diabetic Peripheral Neuropathy in post test indicating the recovery of selected samples in response to intervention.

Graph I – Patient-Rated diabetic polyneuropathy Evaluation of Group A



Pre & Post test values

TABLE - III

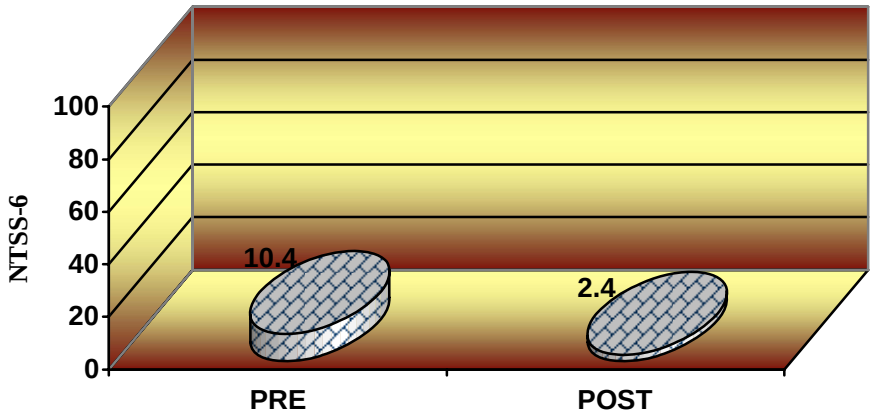
Group – B

Table III represents the mean values, mean difference, standard deviation, and paired‘t’ value of Patient Rated Diabetic Peripheral Neuropathy for group B, who have been subjected to External Electrical Stimulation.

NTSS-6	**Mean**	**Mean difference**	**Standard deviation**	**Paired ‘t’ value**
Pre test	10.40	8	1	30.98
Post test	2.40			

Table III shows the analysis of Patient Rated Diabetic Peripheral Neuropathy; the paired ‘t’ value of pre Vs post sessions of group B was 30.98 at 0.05 level of significance, which was greater than the tabulated value of 2.15. This showed that there was a statistical significant difference in between pre Vs post test results. The pre test mean was 10.40, the post test mean was 2.40 and mean difference was 8 , which showed that there was a decrease in Patient Rated Diabetic Peripheral Neuropathy in post test indicating the recovery of selected samples in response to intervention

Graph II – Patient-Rated diabetic polyneuropathy Evaluation of Group B



Pre & Post test values

TABLE – IV

Table IV represents the comparative mean values, mean difference, standard deviation, and unpaired‘t’ value between group A and group B on Patient Rated Diabetic Peripheral Neuropathy.

NTSS-6	**Mean**	**Mean difference**	**Standard deviation**	**Unpaired ‘t’ value**
Group A	4.76	3.24	0.895	9.92
Group B	8			

Table IV shows the analysis of group A and group B with Patient Rated Diabetic Peripheral Neuropathy. The unpaired‘t’ value of 9.92 was greater than the tabulated ‘t’ value of 2.05 at 0.05 level of significance which showed that there was statistically significant difference between group A and group B. The mean value of group A was 4.76 and the mean value of group B was 8, which showed that there was a greater improvement in group B than group A.

Therefore, the study is rejecting the null hypothesis and accepting the alternate hypothesis.

Graph III - Mean difference of Group A and Group B NTSS-6

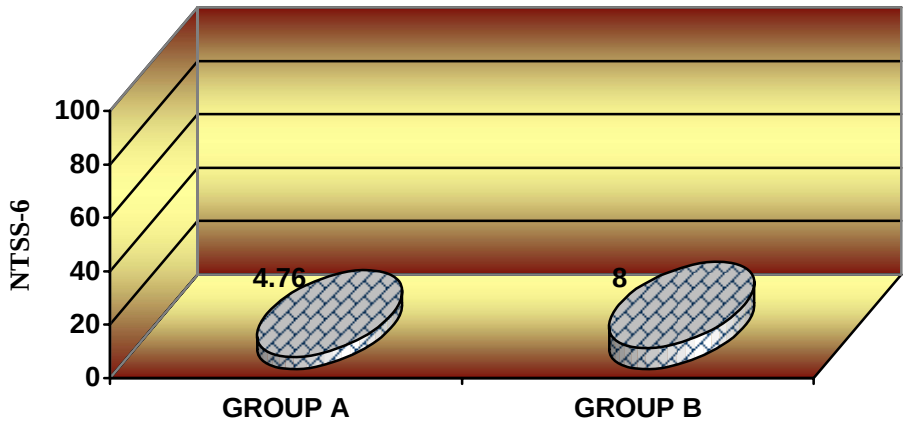


TABLE - V

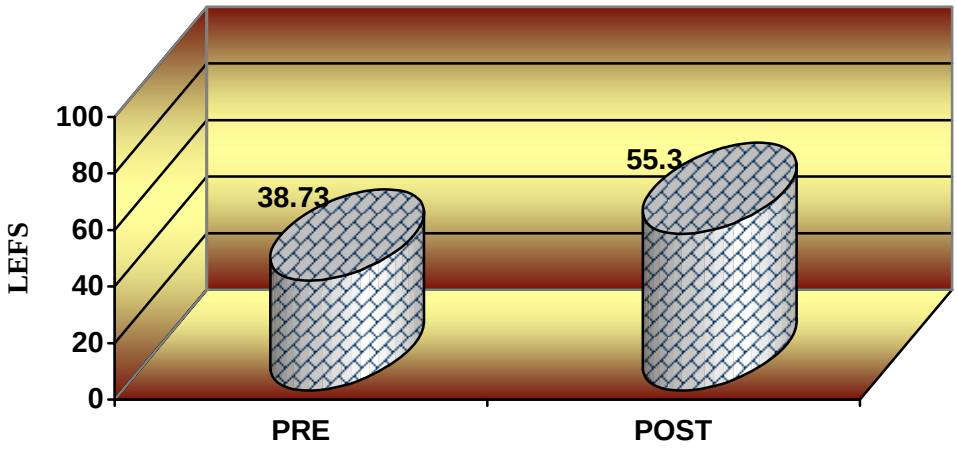
Group – A

Table V represents the mean values, mean difference, standard deviation, and paired ‘t’ value between pre test Vs post test values of Diabetic Peripheral Neuropathy for group A who have been subjected to Transcutaneous electrical nerve stimulation.

LEFS	Mean	Mean difference	Standard deviation	Paired ‘t’ value
Pre test	38.73	16.57	2.472	26
Post test	55.30			

Table V shows the analysis of lower extremity functional scale.; the paired ‘t’ value of pre Vs post sessions of group A was 26 at 0.05 level of significance, which was greater than the tabulated value of 2.15. This showed that there was a statistical significant difference in between pre Vs post test results. The pre test mean was 38.73 , the post test mean was 55.30 and mean difference was 16.57 , which showed that there was an increase in lower extremity functional scale in post test indicating the recovery of selected samples in response to intervention.

Graph IV– LEFS of Group A



Pre & Post test values

TABLE - VI

Group – B

Table VI represents the mean values, mean difference, standard deviation, and paired ‘t’ value of lower extremity functional scale.

For group B, who have been subjected to External electrical muscle stimulator.

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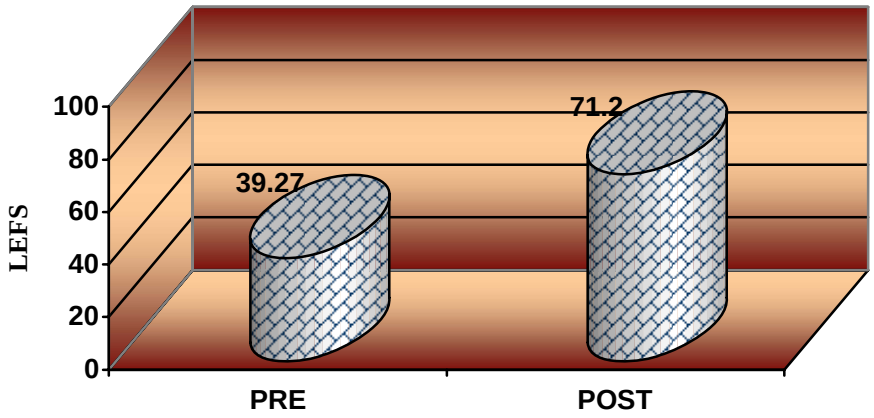
LEFS	Mean	Mean difference	Standard deviation	Paired ‘t’ value
Pre test	39.27	31.93	4.245	28.99
Post test	71.20			

Table VI shows the analysis of lower extremity functional scale, the paired ‘t’ value of pre Vs post sessions of group B was 28.99 at 0.05 level of significance, which was greater than the tabulated value of 2.15. This showed that there was a statistical significant difference in between pre Vs post test results. The pre test mean was 39.27-, the post test mean was 71.20 and mean difference was 31.93, which showed that there was an increase in lower extremity functional scale in post test indicating the recovery of selected samples in response to intervention.

Graph V– LEFS of Group B



Pre & Post test values

TABLE - VII

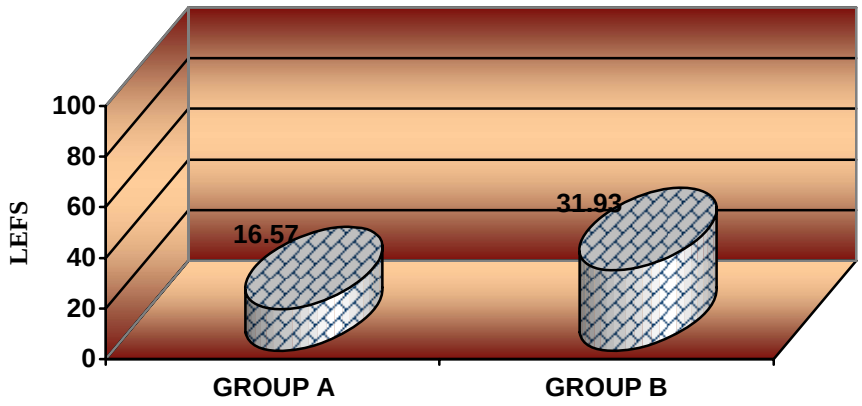
Table VII represents the comparative mean values, mean difference, standard deviation, and unpaired ‘t’ value between group A and group B on lower extremity functional scale.

LEFS	Mean	Mean difference	Standard deviation	Unpaired ‘t’ value
Group A	16.57	15.36	3.358	12.538
Group B	31.93			

Table VII shows the analysis of group A and group B with lower extremity functional scale .The unpaired ‘t’ value of 12.538 was greater than the tabulated ‘t’ value of 2.05 at 0.05 level of significance which showed that there was statistically significant difference between group A and group B. The mean value of group A was 16.57 and the mean value of group B was 31.93, which showed that there was a greater improvement in group B than group A.

Therefore, the study is rejecting the null hypothesis and accepting the alternate hypothesis.

Graph VI - Mean difference of Group A and Group B – LEFS



DISCUSSION

The aim of the study was to compare the effectiveness of external electrical muscle stimulation versus Transcutaneous Electrical Muscle Stimulator in management of diabetic peripheral neuropathy.

L.Reichestein et.al used external electrical muscle stimulation for treatment of patient's diabetic peripheral neuropathy.41 patients were selected and treated. The result showed that external electrical muscle stimulation was found to be effective in treatment of diabetic peripheral neuropathy.

Rose B et.al used Neuropathy Total Symptom Score-6 (NTSS-6), Neuropathy Disability Score (NDS). and external electrical muscle stimulation to assess the diabetic peripheral neuropathy. 16 patient with diabetic peripheral neuropathy were selected and treated with external electrical muscle stimulation. Based on the result the above study was conducted.

Per M.Humpert MD et.al also used Neuropathy Total Symptom Score-6 (NTSS-6) and Neuropathy Disability Score (NDS) are used as parameters.

Based on the results of above studies, it is concluded that Neuropathy Total Symptom Score-6 (NTSS-6), Lower Extremity Functional Scale and Neuropathy Disability Score *(NDS)* could be used to quantify the pain and functional status in diabetic peripheral neuropathy.

In the analysis and interpretation of Neuropathy Total Symptom Score-6 (NTSS-6) in group A:

The paired‘t’ value of 23.02 was greater than the tabulated paired ‘t’ value of 2.15, which showed that there was statistically significant difference at 0.05 level of significance and 14 degrees of freedom between pre and post results. The pre test mean was 10.86, post test mean was 6.1 and mean difference was 4.76, which showed improvements regarding sensation and functional status in response to transcutaneous electrical nerve stimulation for 4 weeks.

In the analysis and interpretation of Lower Extremity Functional Scale in group A:

The paired‘t’ value of 26 was greater than the tabulated paired ‘t’ value of 2.15, which showed that there was statistically significant difference at 0.05 level of significance and 14 degrees of freedom between pre and post results. The pre test mean was 38.73, post test mean was 55.30 and mean difference was 16.57, which showed improvements regarding sensation for 4 weeks.

The above study results support the result of present study in which Transcutaneous Electrical nerve Stimulator has got improvement in above mentioned parameters in group A patients with diabetic peripheral neuropathy.

In the analysis and interpretation of Neuropathy Total Symptom Score-6 (NTSS-6) in group B:

The paired‘t’ value of 30.98 was greater than the tabulated paired ‘t’ value of 2.15, which showed that there was statistically significant difference at 0.05 level of significance and 14 degrees of freedom between pre and post results. The pre test mean was 10.40, post test mean was 2.40 and mean difference was 8, which showed improvements regarding pain and functional status in response to external electrical muscle stimulation for 4 weeks.

In the analysis and interpretation of Lower Extremity Functional Scale B:

The paired‘t’ value of 28.99 was greater than the tabulated paired ‘t’ value of 2.15 , which showed that there was statistically significant difference at 0.05 level of significance and 14 degrees of freedom between pre and post results. The pre test mean was 39.27, post test mean was 71.20 and mean difference was 31.93, which showed improvements regarding **Lower Extremity Functional Scale** in response to external electrical muscle stimulation for 4 weeks.

The study results of l. Reichstein et al .supports the result of present study in which external electrical muscle stimulation has got improvement in above mentioned parameters in group B patients with diabetic peripheral neuropathy.

IN THE COMPARISON OF GROUP – A AND GROUP – B:

In the analysis and interpretation of Neuropathy Total Symptom Score-6 (NTSS-6) between group A and group B:

In the analysis and interpretation of **Neuropathy Total Symptom Score-6 (NTSS-6)**, the unpaired 't' value of 9.92 was greater than the tabulated 't' value of 2.05, at 0.05 level of significance and 28 degrees of freedom, which showed that there was statistically significant difference between pre test Vs post test results of group A and group B. The mean value of group A was 4.76, mean value of group B was 8 and mean difference was 3.24 which showed that there was significant improvements regarding pain and functional status in group B compared to group A in response to treatment.

In the analysis and interpretation of Lower Extremity Functional Scale between group A and group B:

In the analysis and interpretation of **Lower Extremity Functional Scale**, the unpaired 't' value of 12.538 was greater than the tabulated 't' value of 2.05, at 0.05 level of significance and 28 degrees of freedom, which showed that there was statistically significant difference between pre test Vs post test results of group A and group B. The mean value of group A was 16.57, mean value of group B was 31.93 and mean difference was 15.36 which showed that there was significant improvements regarding **Lower Extremity Functional Scale** in group B compared to group A in response to treatment.

Based on the statistical analysis and interpretation of the results, the present study showed that there was significant improvement regarding pain, functional status, **Neuropathy Total Symptom Score-6** (**NTSS-6)** and **Lower Extremity Functional Scale** values in patients with **diabetic peripheral neuropathy** treated with external electrical muscle stimulation than with Transcutaneous electrical nerve stimulation .

Therefore, the present study is accepting alternate hypothesis and rejecting null hypothesis.

REASON FOR IMPROVEMENT FOR EXTERNAL ELECTRICAL MUSCLE STIMULATION.

- External electrical muscle stimulation activates the dorsal column that inhibits the c fibers thus interrupting gating pain in put so there by pain is been reduced.

- External electrical muscle stimulation suggest a improvement in the skin perfusion this due to electrical muscle stimulation act as a neural vasodilatation.

- The high frequency and twin peak properties of the current produce neural vasodilatation on both place of electrode.

- Activates large diameter sensory nerve there by inhibits sympathetic vasoconstriction neuron activity.

- Activates small to medium sized sensory neurons to release vasodilatory neurotransmitter.

- Electrical muscle stimulation to the lower limb increases the up take of carbohydrate in lower limb than voluntary cycling exercise.

- Unlike during voluntary contraction the larger motor neuron innervating fast twitch fiber is the first one to be activated, owing to their larger neuron axon s with low in put resistance against electrical muscle stimulation.

- External electrical muscle stimulation increases insulin sensitivity and GLUT-1 and GLUT-4 distribution is being improved.

- Micro vascular blood supply and insulin resistance improved in diabetic peripheral neuropathy patients.

REASON FOR IMPROVEMENT FOR TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

- TENS reduces the conduction velocity of the afferent fibers so there by reduces the pain sensation.

- The peripheral conduction is slowed the volume of nociceptive traffic is reduced and this will reduce over all perception of pain.

- TENS releases potent vasodilator, calcitonin which is gene related peptide. So there is observed increased in the peripheral blood flow.

REASON FOR IMPROVEMENT FOR EXTERNAL ELECTRICAL MUSCLE STIMULATION THAN TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

- External electrical muscle stimulation increases insulin sensitivity and GLUT-1 and GLUT-4 distribution is being improved.

- Micro vascular blood supply and insulin resistance improved in diabetic peripheral neuropathy patients.

- External electrical muscle stimulation activates the dorsal column that inhibits the c fibers thus interrupting gating pain in put so there by pain is been reduced.

SUMMARY AND CONCLUSION

Summary:

The objective of the study was to compare the effect of external electrical muscle stimulation versus Transcutaneous Electrical Muscle Stimulator in management of diabetic peripheral neuropathy.

To conduct the study, a total number of 30 patients, were selected by random sampling method after the consideration of inclusion and exclusion criteria. The informed consents were obtained from subjects individually.

NTSS-6 and LEFS were taken as parameters to measure the changes.The pre treatment data were collected for group A and group B subjectes and computed.

Group A were given TENS and Group B wrer given external electrical muscle stimulation treatment daily. The result of the same parameter were recorded for comparison after three weeks of treatment.

The paired 't' test was used to compare the pre versus post treatment result of Group A and Group B seperately.The unpaired 't'test was used to compare the mean difference of Group A and Group B.

In the analysis and interpretation of Neuropathy Total Symptom Score-6 (NTSS-6), the unpaired 't' value of 9.92 was greater than the tabulated 't' value of 2.05, at 0.05 level of significance and 28 degrees of freedom, which showed that there was statistically significant difference between pre test Vs post test results of group A and group B. The mean value of group A was 4.76, mean value of group B was 8 and mean difference was 3.24 which showed that there was significant

improvements regarding pain and functional status in group B compared to group A in response to treatment.

In the analysis and interpretation of Lower Extremity Functional Scale, the unpaired ‘t’ value of 12.538 was greater than the tabulated ‘t’ value of 2.05, at 0.05 level of significance and 28 degrees of freedom, which showed that there was statistically significant difference between pre test Vs post test results of group A and group B. The mean value of group A was 16.57, mean value of group B was 31.93 and mean difference was 15.36 which showed that there was significant improvements regarding Lower Extremity Functional Scale in group B compared to group A in response to treatment.

Conclusion:

This study shows that there was reduction in cold, warm ,cold pain threshold ,heat pain threshold, vibration perception threshold and touch perception threshold diabetic peripheral neuropathy after treatment with external electrical muscle stimulation.

Thus the study concluded that external electrical muscle stimulation is effective treatment for diabetic peripheral neuropathy and Neuropathy Total Symptom Score-6 (NTSS-6) and Lower Extremity Functional Scale could be used as the assessment tools for cold, warm ,cold pain threshold ,heat pain threshold, vibration perception threshold and touch perception threshold

RECOMMENDATIONS

- A similar study can be conducted for reducing the blood sugar level in type II Diabetic patients.

- The Lower Extremity Functional Scale (LEFS) Neuropathy Total Symptom Score-6 (NTSS-6) and Neuropathy Disability Score (NDS) parameters can be used for other poly neuropathy conditions.

- The effectiveness of transcutaneous electrical nerve stimulation in reducing the pain in diabetic peripheral neuropathy.

- The effectiveness of Transcutaneous electrical nerve stimulation and external electrical muscle stimulation in stroke, peripheral nerve lesion and neuropathy conditions.

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APPENDIX

DEFINITION OF TERMS

- **Diabetic peripheral neuropathy**

The term Diabetic peripheral neuropathy encompasses a wide range of disorders in which the nerves outside of the brain and spinal cord—peripheral nerves—have been damaged. Peripheral neuropathy may also be referred to as peripheral neuritis, or if many nerves are involved, the terms polyneuropathy or polyneuritis may be used.

- Transcutaneous electrical nerve stimulation (TENS)

Transcutaneous electrical nerve stimulation (TENS) is the use of electric current produced by a device to stimulate the nerves for therapeutic purposes. TENS by definition covers the complete range of transcutaneously applied currents used for nerve excitation although the term is often used with a more restrictive intent, namely to describe the kind of pulses produced by portable stimulators used to treat pain.

- External electrical muscle stimulation

Electrical muscle stimulation (EMS), also known as neuromuscular electrical stimulation (NMES) or electromyo stimulation is the elicitation of muscle contraction using electric impulses. The impulses are generated by a device and delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. The impulses mimic the action potential coming from the central nervous system, causing the muscles to contract. The electrodes are generally pads that adhere to the skin.

- Neuropathy Total Symptom Score-6(**NTSS-6).**

The NTSS-6 questionnaire was developed to evaluate the frequency and intensity of individual neuropathy sensory symptoms identified frequently by patients with DPN (ie, 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).

- Lower Extremity Functional Scale (LEFS).

The Lower Extremity Functional Scale (LEFS) can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention

PARAMETER

Neuropathy Total Symptom Score-6 (**NTSS-6)**

Subjective Peripheral Neuropathy Screen Questionnaire

Full Name: _____

Date: _____

Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel, Thank you.

- Do you ever have legs and/or feet that feel numb? Yes No.
- Do you ever have any burning pain in your legs and/or feet? Yes No.
- Are your feet too sensitive to touch? Yes No
- Do you get muscle cramps in your legs and/or feet? Yes No
- Do you ever have any prickling or tingling feelings in your legs or feet? Yes No
- Does it hurt at night or when the covers touch your skin? Yes No
- When you get into the tub or shower, are you unable to tell the hot water from the cold water with your feet? Yes No
- Do you ever have any sharp, stabbing, shooting pain in your feet or legs? Yes No
- Have you experienced an asleep feeling or loss of sensation in your legs or feet? Yes No

- Do you feel weak when you walk? Yes No
- Are your symptoms worse at night? Yes No
- Do your legs and/or feet hurt when you walk? Yes No
- Are you unable to sense your feet when you walk? Yes No
- Is the skin on your feet so dry that it cracks open? Yes No
- Have you ever had electric shock-like pain in your feet or legs? Yes No .

The Lower Extremity Functional Scale (LEFS)

Overview: The Lower Extremity Functional Scale (LEFS) can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention. The authors are from McMaster University in Hamilton Ontario.

Patient instructions: Today does you or would you have any difficulty at all with these activities?

Activities (20):

- Any of your usual work housework or school activities
- Your usual hobbies recreational or sporting activities.
- Getting into or out of the bath
- Walking between rooms
- Putting on your shoes or socks
- Squatting
- Lifting an object like a bag of groceries from the floor
- Performing light activities around your home
- Performing heavy activities around your home

- getting into or out of a car
- walking 2 blocks (about 1/6th mile or about 250 meters)
- walking 1 mile (1.6 km)
- going up or down 10 steps (about 1 flight of stairs)
- standing for 1 hour
- sitting for 1 hour
- running on even ground
- running on uneven ground
- making sharp turns while running fast
- hopping
- rolling over in bed

Response	Points
unable to perform activity or extreme difficulty	0
quite a bit of difficulty	1
moderate difficulty	2
a little bit of difficulty	3
no difficulty	4

The Lower Extremity Functional Scale score = sum (points for all 20 activities)

Interpretation:

- minimum score: 0
- maximum score: 80
- The lower the score the greater the disability.
- The Minimal Detectable Change (MDC) is 9 scale points.

• The Minimal clinically Important Difference (MCID) is 9 scale points.

Percent of maximal function =

= (LEFS score) / 80 * 100

TECHNIQUE:

Type 2 DM patients, who were only treated with a diet and/or oral Anti diabetics were included in this 12 week study. After an Introductory phase of 2 weeks with the use of an EMS unit, the treatment was given at the patient's disposal. On average, the test Persons used the unit daily during the following 4months.

Alternately the electrodes were placed in the area of the Musculature of thighs and the shank. The treatment was given for twenty min for each patient. Each period of application and intensity was recorded by the units.

After this 4months period of treatment the units were given back. The course of the above mentioned parameters. A square-wave biphasic pulses of 0.2-ms duration at a frequency of 20 Hz with a duty cycle of 1-s stimulation/1-s pause**,** because our laboratory has previously reported that parameters used can induce the highest $\dot{V}o_2$ with this procedure. Both muscle

groups (lower legs and tight) were sequentially stimulated to co contract in an isometric manner elicited from an electrical stimulator.

Fig- 1: **Treatment given with stimulator**.

Fig 2: Treatment given with TENS.

INFORMED CONSENT TO PARTICIPATE VOLUNTARILY IN A RESEACH INVESTICATION

NAME :

AGE :

SEX :

OCCUPATION :

ADDRESS FOR COMMUNICATION :

DECLARATION

I have fully understood the nature and purpose of the study. I accept to be a subject in this study. I declare that the above information is true to my knowledge.

DATE :

PLACE :

Signature of the subject

ASSESSMENT CHART

NAME :

AGE :

SEX :

SIDE :

MODE OF TREATMENT : External Electrical Muscle Stimulation versus TENS

MEASUREMENT :

PARAMETER	BEFORE TREATMENT	AFTER TREATMENT
NTSS – 6 LEFS		