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Effectiveness of Transcutaneous Electrical Nerve Stimulation In Chronic Painful Diabetic Neuropathy

Tanmay Kumar Bose, Mr.M.Karthikeyan

Physiotherapy Department ,Srm College of Physiotherapy ,SRM University India

A B S T R A C T

Diabetes mellitus is caused by an insufficient insulin medicated response to blood glucose, people with the disorder classified as being Type I or Type II Diabetes. Whereas studies stating that Pain reduction using Transcutaneous Electrical Nerve Stimulation (TENS) in case of Chronic Painful Diabetic Neuropathy (PDN) are limited. The aim of the study is to find whether the Transcutaneous Electrical Nerve Stimulation (TENS) is effective for Chronic Painful Diabetic Neuropathy (PDN) in case of Type 2 Diabetes Mellitus. Total of 45 patients are diagnosed as Painful Diabetic Neuropathy (PDN) by neurologist have been selected for convenience sampling & divided into 3 groups after consideration of selection criteria at S.S.K.M.Medical College & Post Graduate with a duration of 4 weeks. In this Experimental study author taken the Group A (15 subjects) : receives only Medication (as prescribed by the Physician) for Painful Diabetic Neuropathy (PDN),Group B (15 subjects) : receives Medication (as prescribed by the Physician) and Transcutaneous Electrical Nerve Stimulation (TENS) for PDN and Group C (15 subjects) : receives Medication and SHAM Transcutaneous Electrical Nerve Stimulation (TENS) for PDN (with TENS ,Frequency 2 - 70 HZ.Wave from :Biphasic, Pulse width: 4 ms,Intensity:> 35 mA, and Treatment time : 40 min) .Hence this study is taken to find whether TENS is really effective or a mere Placebo in Chronic Painful Diabetic Neuropathy. The Outcome measure is evaluated by VISUAL ANALOG SCALE (VAS) to analyze the pain and Pain Graded Scale.- (Howard J Marshall) The author found that In Group A, at the end of fourth week t value of VAS shows 2.981 and PGS 2.646 & for Group B, t value of VAS 10.893 and PGS 6.813 & for Group C, t value of VAS 5.154 and PGS 2.256. So the Group B is more significant than Group A and Group C.In this study, we observed that the Transcutaneous Electrical Nerve Stimulation (TENS) reduce pain & discomfort of Chronic Painful Diabetic Neuropathy. This non-invasive treatment is safe, with no side effects. It appears that such a non pharmacological modality could be useful for symptomatic relief and offers a potential treatment option.

Keywords: Transcutaneous Electrical Nerve Stimulation (TENS), Diabetic Neuropathy, Type 2 Diabetes Mellitus

1. Introduction

Diabetes mellitus is caused by an insufficient insulin medicated response to blood glucose, people with the disorder classified as being Type 1 or Type 2 Diabetes2.

India leads the world with largest number of diabetic subjects being termed the "diabetes capital of the world". According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 20253.

Painful Diabetic Neuropathy (PDN) is a common complication of Diabetic Neuropathy (Type II) and it affects approximately>36% of NIDDM individuals6.

Painful Diabetic Neuropathy symptom such as Burning, Pins and Needles pricks sensation, schooting pain and hyperesthesia has also been reported7. Pain is usually worst at night and may disrupt the patient sleep8. Assessment of PDN should include monofilament, vibratory, and pinprick tests9. Reflexes and the strength and flexibility of the toes, foot, and ankle should also be assessed9, 10.Patient suffering from Painful Diabetic Neuropathy may be unable to maintain their posture11, 12.

* *Corresponding author.*
E-mail address: tanmaykbose@gmail.com

As the aetiology and pathogenesis of Painful symptom induced by Diabetic Neuropathy are poorly understood, treatment (Medical Treatment) is largely symptomatic 5.

Transcutaneous electrical nerve stimulation (TENS) is one of the most commonly used forms of electroanalgesia,such as low back pain (LBP), myofascial13 and arthritic pain 14,15, sympathetically mediated pain, bladder incontinence, neurogenic pain16, visceral pain and postsurgical pain17,18.Because many of these studies were uncontrolled, there has been ongoing debate about the degree to which TENS is more effective than placebo in reducing pain19. For Painful Diabetic Neuropathy pain is the more common complication that is carried by the A delta fiber, so blocking of pain gait can reduce the pain20.

Some studies says that the role of TENS is merely placebo for pain & there is lack of evidence for the effectiveness of TENS in chronic pain24. Hence this study was taken.

2. AIM OF THE STUDY

To find whether the Transcutaneous Electrical Nerve Stimulation (TENS) is effective for Chronic Painful Diabetic Neuropathy (PDN) in case of Type 2 Diabetes Mellitus.

3. NEED FOR THE STUDY

Literature supporting the usage of non-pharmacologic treatment, Transcutaneous Electrical Nerve Stimulation (TENS), in Painful Diabetic Neuropathy (PDN) in case of Type 2 Diabetes Mellitus is limited. Hence to fulfill this need, this study was done.

4. HYPOTHESES

Null hypothesis:

There is NO significant effect of TENS on Chronic Painful Diabetic Neuropathy.

Alternate hypothesis:

There is significant effect of TENS on Chronic Painful Diabetic Neuropathy.

5. REVIEW OF LITERATURE

Jin DM,Xu Y,Geng DF et al(2010): Stated about the physiology of the pain caused by Diabetic Neuropathy [20].

Scott R Votey, MD, Anne L Peters, MD, CDE et al (Sep 23, 2010):Concluded that Type 2 diabetes is essentially equal in women and men in all populations & type 2 diabetes mellitus still occurs most commonly in adults aged 40 years or older[28].

Harrison principle of internal medicine, 17th edition, (2009): Stated about the type of diabetes mellitus[2].

Cipriano G Jr, de Camargo Carvalho AC, Bernardelli GF et al (Aug 2008): Stated that the short-term transcutaneous electrical nerve stimulation effective after cardiac surgery and effectiveness on pain, pulmonary function and electrical muscle activity[17].

V. Mohan, S. Sandeep, R. Deepa et al (March 2007): Stated about the epidemiology of type 2 diabetes in Indian scenario and stated that the "diabetes capital of the world"[3].

Law PP, Cheing GL et al (Sep 2004): Documented that optimal stimulation frequency of transcutaneous electrical nerve stimulation is effective on people with knee osteoarthritis[14].

Ottawa Panel et al (Nov 2004): Stated that tens is effective for the management of rheumatoid arthritis in adults evidence-based clinical practice guidelines for electrotherapy and thermotherapy interventions in the management of rheumatoid arthritis in adults[15].

Forst t ,Nguyen m, Forst s,Disselhoff B, Pohlmann T ,Pfutzner A et al (June 2004): Stated that TENS units are used in alleviate neuropathic pain."Impact of low frequency transcutaneous
electrical nerve stimulation on symptomatic diabetic neuropathy using the new salutaris device"[16].

Daousi C, MacFarlane IA, Woodward A et al (2004): Stated about the occurrence of Chronic painful peripheral neuropathy in an urban community and controlled comparison of people with and without diabetes[30].

Krishnan STM, Rayman G et al (2003): Stated about the assessment of painful diabetic neuropathy[9].

Vileikyte L, Peyrot M et al (2003): Documented about the assessment of PDN development and validation of a neuropathy- and foot ulcer-specific quality of life instrument[10].

Poncelet AN et al (2003): Documented about the most distressing symptoms that people can suffer from is neuropathic pain and parasthesia, Risk factors, patterns of presentation, diagnosis, and treatment[5].

Conner-Kerr T, Templeton MS et al (2002): Documented on there is increased chronic fall of risk among aged individuals with type 2 diabetes[12].

Abbott CA, Carrington AL et al (2002): Documented that Peripheral neuropathy is one of the most common complications of both type 1 and type 2 diabetes. In a population-based study incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort[29].

6. METHODOLOGY

MEASUREMENT:

- VISUAL ANALOG SCALE (VAS) [25]
- Pain Graded Scale.- *(Howard J Marshall)* [26]

END POINT: The measurement was taken before & after 4weeks of treatment.

STUDY DESIGN: Experimental Design.

SAMPLING & SAMPLING TECHNIQUE:

Total of 45 patients are diagnosed as Painful Diabetic Neuropathy (PDN) by neurologist have been selected for convenience sampling & divided into 3 groups after consideration of selection criteria.

- Group A (15 subjects): treated by medication as prescribed by physician for Painful Diabetic Neuropathy (PDN).
- Group B (15 subjects): treated by medication as prescribed by their physician and will receive Transcutaneous Electrical Nerve Stimulation (TENS).
- Group C (15 subjects): treated by medication as prescribed by their physician and will receive SHAM Transcutaneous Electrical Nerve Stimulation (TENS) [27].

SETTING OF THE STUDY:

S.S.K.M. Medical College & Post Graduate Institute of Medical Research, Kolkata.

SELECTION CRITERIA:

INCLUSION CRITERIA

- Both Men and Women [28]
- Age: 40 to 70 years[28]
- Documented Type II Diabetes and symptom of Painful Diabetic Neuropathy involving Right lower extremity for >2 months[29, 30].
- Chronic (more than one year) Diabetes Mellitus patients.
- Grades up to 2 on Pain graded Scale [26].

EXCLUSION CRITERIA

- Having clinical evidence of vascular insufficiency of leg or feet (history of Claudication, Discoloration of skin, ulceration) [26.]
- Any relevant Cardiac history[26].
- Psychiatric disease
- Substance abuse including alcohol
- Significant Renal disease[26.]
- Liver disease[26.]
- Patient with corticosteroid or chemotherapeutic agent.
- Grade 3 and above on Pain Graded Scale[26].
- Sever sensory loss
- Drug induced Neuropathy[31]
- Malignancy

MATERIALS USED FOR STUDY:

- Digital Biothesiometer- VIBROMETER (VPT) [32]
- Transcutaneous Electrical Nerve Stimulator (TENS) machine
- Micro pore tape (3mm)
- Gel

- Pencil
- Scale

PROCEDURE:

Total of 45 subjects have been divided into Painful Diabetic Neuropathy (PDN).3groups by convenience sampling following a complete assessment. All the subjects have been explained about their condition & mode of treatment is given.

Subjects who were involved in the study are suitable for inclusion criteria.

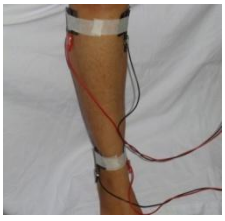
- Group A (15 subjects): Patient made to sit comfortably, at the pre-therapy stage Visual Analog Scale & Pain Graded Scale *(Howard J Marshall)* is noted.

  will receive only medication as prescribed by physician for Painful Diabetic Neuropathy (PDN).
- Group B (15 subjects): Patient made to sit comfortably, at the pre-therapy stage Visual Analog Scale & Pain Graded Scale *(Howard J Marshall)* is noted.

will receive medication as prescribed by their physician and Transcutaneous Electrical Nerve Stimulation (TENS) for three consecutive days in a week for Painful Diabetic Neuropathy (PDN).

- Group C (15 subjects): Patient made to sit comfortably, at the pre-therapy stage Visual Analog Scale & Pain Graded Scale *(Howard J Marshall)* is noted.

will receive medication as prescribed by their physician and SHAM Transcutaneous Electrical Nerve Stimulation (TENS) for three consecutive days in week for Painful Diabetic Neuropathy (PDN) .



Placement of electrodes of TENS in Right lower extremity

POST THERAPY MEASUREMENT

Group B & C: At end of every week treatment session & at the end of the 4week Visual Analog Scale and Pain Graded Scale *(Howard J Marshall).*

Group A: At end of every week of Drug treatment session & at the end of the 4week visual Analog Scale and Pain Graded Scale *(Howard J Marshall)*

DATA ANALYSIS

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	VAS - PRE TEST - VAS - END OF FIRST WEEK	.2467	.8061	.2081	-.1997	.6931	1.185	14	.256
Pair 2	VAS - PRE TEST - VAS - END OF SECOND WEEK	.5933	.8472	.2188	.1241	1.0625	2.712	14	.017
Pair 3	VAS - PRE TEST - VAS - END OF THIRD WEEK	.6267	.8362	.2159	.1636	1.0897	2.902	14	.012
Pair 4	VAS - PRE TEST - VAS - END OF FOURTH WEEK	.7667	.9962	.2572	.2150	1.3183	2.981	14	.010

Comparing the PRE test and POST test using Visual Analog Scale in group A

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	VAS - PRE TEST - VAS - END OF FIRST WEEK	1.5333	.8516	.2199	1.0617	2.0049	6.973	14	.000
Pair 2	VAS - PRE TEST - VAS - END OF SECOND WEEK	2.9133	1.0842	.2799	2.3129	3.5138	10.407	14	.000
Pair 3	VAS - PRE TEST - VAS - END OF THIRD WEEK	3.6533	1.3109	.3385	2.9274	4.3793	10.794	14	.000
Pair 4	VAS - PRE TEST - VAS - END OF FOURTH WEEK	3.8533	1.3700	.3537	3.0946	4.6120	10.893	14	.000

Comparing the PRE test and POST test using Visual Analog Scale in group B

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	VAS - PRE TEST - VAS - END OF FIRST WEEK	.5400	.5604	.1447	.2297	.8503	3.732	14	.002
Pair 2	VAS - PRE TEST - VAS - END OF SECOND WEEK	.8933	.6041	.1560	.5588	1.2279	5.727	14	.000
Pair 3	VAS - PRE TEST - VAS - END OF THIRD WEEK	.9133	.7434	.1919	.5016	1.3250	4.758	14	.000
Pair 4	VAS - PRE TEST - VAS - END OF FOURTH WEEK	1.0933	.8216	.2121	.6384	1.5483	5.154	14	.000

Comparing the PRE test and POST test using Visual Analog Scale in group C

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	PGS - PRE TEST - PGS - END OF FIRST WEEK	.333	.488	.126	.063	.604	2.646	14	.019
Pair 2	PGS - PRE TEST - PGS - END OF SECOND WEEK	.333	.488	.126	.063	.604	2.646	14	.019
Pair 3	PGS - PRE TEST - PGS - END OF THIRD WEEK	.333	.488	.126	.063	.604	2.646	14	.019
Pair 4	PGS - PRE TEST - PGS - END OF FOURTH WEEK	.333	.488	.126	.063	.604	2.646	14	.019

Comparing the PRE test and POST test using Pain Graded Scale in group A

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	PGS - PRE TEST - PGS - END OF FIRST WEEK	.267	.458	.118	.013	.520	2.256	14	.041
Pair 2	PGS - PRE TEST - PGS - END OF SECOND WEEK	.800	.676	.175	.426	1.174	4.583	14	.000
Pair 3	PGS - PRE TEST - PGS - END OF THIRD WEEK	1.067	.704	.182	.677	1.456	5.870	14	.000
Pair 4	PGS - PRE TEST - PGS - END OF FOURTH WEEK	1.467	.834	.215	1.005	1.928	6.813	14	.000

Comparing the PRE test and POST test using Pain Graded Scale in group B

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	PGS - PRE TEST - PGS - END OF FIRST WEEK	.267	.458	.118	.013	.520	2.256	14	.041
Pair 2	PGS - PRE TEST - PGS - END OF SECOND WEEK	.200	.414	.107	-.029	.429	1.871	14	.082
Pair 3	PGS - PRE TEST - PGS - END OF THIRD WEEK	.200	.414	.107	-.029	.429	1.871	14	.082
Pair 4	PGS - PRE TEST - PGS - END OF FOURTH WEEK	.267	.458	.118	.013	.520	2.256	14	.041

Comparing the PRE test and POST test using Pain Graded Scale in group C

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
VAS - PRE TEST	Between Groups	1.868	2	.934	1.958	.154
	Within Groups	20.035	42	.477		
	Total	21.903	44			
VAS - END OF FIRST WEEK	Between Groups	10.979	2	5.490	5.212	.010
	Within Groups	44.233	42	1.053		
	Total	55.212	44			
VAS - END OF SECOND WEEK	Between Groups	39.510	2	19.755	22.149	.000
	Within Groups	37.460	42	.892		
	Total	76.970	44			
VAS - END OF THIRD WEEK	Between Groups	71.521	2	35.761	33.899	.000
	Within Groups	44.307	42	1.055		
	Total	115.828	44			
VAS - END OF FOURTH WEEK	Between Groups	74.041	2	37.021	29.035	.000
	Within Groups	53.551	42	1.275		
	Total	127.592	44			

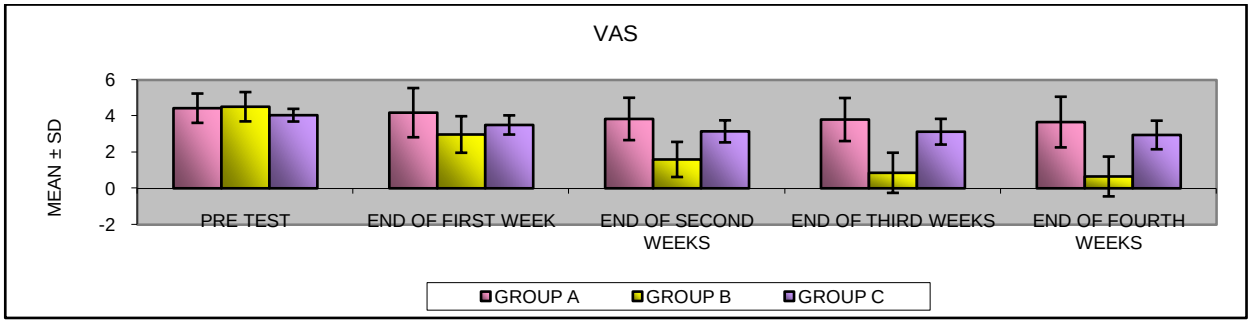
In-between Group comparison in Pain Graded Scale
The mean difference is significant at a level of .05

ANOVA

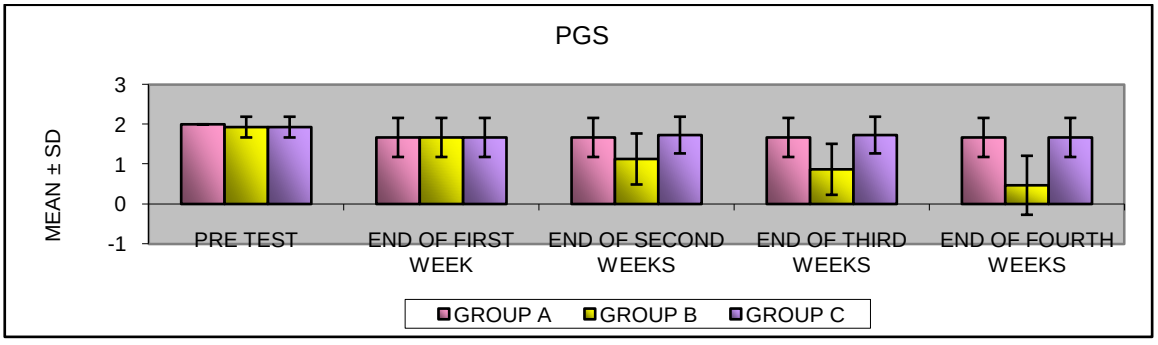
		Sum of Squares	df	Mean Square	F	Sig.
PGS - PRE TEST	Between Groups	.044	2	.022	.500	.610
	Within Groups	1.867	42	.044		
	Total	1.911	44			
PGS - END OF FIRST WEEK	Between Groups	.000	2	.000	.000	1.000
	Within Groups	10.000	42	.238		
	Total	10.000	44			
PGS - END OF SECOND WEEK	Between Groups	3.244	2	1.622	5.678	.007
	Within Groups	12.000	42	.286		
	Total	15.244	44			
PGS - END OF THIRD WEEK	Between Groups	6.978	2	3.489	12.211	.000
	Within Groups	12.000	42	.286		
	Total	18.978	44			
PGS - END OF FOURTH WEEK	Between Groups	14.400	2	7.200	21.000	.000
	Within Groups	14.400	42	.343		
	Total	28.800	44			

In-between Group comparison in Pain Graded Scale
At the end of IV week P < 0.001, hence it is Significant.

VISUAL ANALOG SCALE SCORING



PAIN GRADED SCALE SCORING



7. RESULTS

In the present study the statistical value shows that the post mean values of VAS and PGS at the end of fourth week are 29.034 and 21.000 in Group B. The significant P value is less than 0.001 in both the test and hence it shows 99.9 percent significant.

As the F value increased the degree of significant is increased.

In Group A, at the end of fourth week t value of VAS shows 2.981 and PGS 2.646 & for Group B, t value of VAS 10.893 and PGS 6.813 & for Group C, t value of VAS 5.154 and PGS 2.256. So the Group B is more significant than Group A and Group C.

8. DISCUSSION

The Diabetic Neuropathy is most common and troublesome complication, which affects lower extremities. Type II Diabetes mellitus is universally accepted that has potent which predisposes to atherogenesis (thickening of blood vessels).The increased thickness of the small blood vessel is associated with neuropathy in diabetic subjects.

Though Chronic PDN has involvement of both the Lower extremities, we have taken only the Right LE in our study for homogenecity hence to avoid the possible bias. Medications (Insulin, Metformin, etc.) prescribed by the Physician for Type II DM in PDN varies for patients. Hence the names of the medicines were not mentioned in our study.

We have shown that the Transcutaneous Electrical Nerve Stimulation (TENS) can reduce the pain and discomfort caused by type II Diabetic Mellitus. This non-pharmacological form of treatment was well tolerated and might offer a new option for symptomatic relief in Painful Diabetic Neuropathy.

This study was done with 45 type II Diabetes mellitus patients with Painful Diabetic Neuropathy (PDN) at S.S.K.M. Medical College & Post Graduate Institute of Medical Research, Kolkata and results obtained from the tables indicate that actual TENS of Right lower extremity (1 inch below the Knee joint line medially, 1 inch the below the Knee joint at the Neck of fibula, Just above the Medial Malleolus, Just above the Lateral Malleolus) in chronic Painful Diabetic Neuropathy (PDN) patients, reduced pain in Group B (Mean Age = 51.866 yr) (Actual Transcutaneous Electrical nerve Stimulation for Painful Diabetic Neuropathy and medication for glycemic control) than Group A (Mean Age = 54 yr) (only medication) and Group C (Mean Age = 50.6 yr) (SHAM Transcutaneous Electrical nerve Stimulation for Painful Diabetic Neuropathy and medication for glycemic control).

The Pre-test and Post-test scores were measured and data were analyzed with statistical interference. Participants in this study received the Transcutaneous Electrical Nerve Stimulation (TENS) for 40 min/day and three consecutive days in a week for 4 weeks.

Dinesh Kumar, Howard J.Marshall, stated that Transcutaneous Electrical Nerve Stimulation (TENS) reduce the pain and discomfort associated with Peripheral Neuropathy in a patient with type II Diabetic Mellitus.

Inspired to take up this study a bit further, in this study three Groups are included and the study proved that it is statistically significant in introducing and clinical decision making in the treatment programmed for chronic Painful Diabetic Neuropathy (PDN).

In the present study the statistical value of this study shows that the post mean values of VAS and PGS at the end of fourth week are 29.034 and 21.000 in Group B. The significant P value is less than 0.001 ($P<0.001$) in both the test and hence it shows 99.9 percent significant.

As the f value increased the degree of significant is increased.

In group A, at the end of fourth week t value of VAS shows 2.981 and PGS 2.646 & the p value of VAS is 0.10, which is not significant and the p value of PGS is 0.19 that is also not significant .

For group B, t value of VAS 10.893 and PGS 6.813 and the p value of VAS is 0.000 that is significant and p value of PGS is 0.000 that is also significant.

In group C, t value of VAS 5.154 and PGS 2.256 and the p value of VAS is 0.000 that is significant but the p value of pgs is 0.041 which is not significant. So the group B is more significant than group A and group C.

Valdimir kaya ,Md et.all, stated that the currently proposed mechanisms by which TENS produces neuro-modulation includes the following:

- Presynaptic inhibition in the dorsal horn of the spinal cord
- Endogenous pain control (via endorphins, enkephalins, and dynorphins)
- Direct inhibition of an abnormally excited nerve
- Restoration of afferent input

We describe the use of TENS to treat lower extremity neuropathy pain in a patient with painful diabetic Neuropathy in case of type II diabetic mellitus. The modality was delivered using electrode positioned over the Right lower extremity.

1 inch below the Knee joint line medially ,1 inch below the Knee joint at the Neck of fibula.,Just above the Medial Malleolus.,Just above the Lateral Malleolus

With the TENS, Frequency 2 - 70 HZ, Wave from: Biphasic, Pulse width: 4 ms, Intensity: > 35 mA, Treatment time: 40 min.

Results suggest that SHAM TENS & only MEDICATION for Painful Diabetic Neuropathy is not as effective as actual TENS.

This approach is consistently successful and experience with patients treated at the endocrine department suggests that treatment given for long duration can be more beneficial for long lasting diabetic neuropathic pain.

In summary, our study suggests that TENS is useful non-invasive, non-pharmacological treatment for the management of chronic painful diabetic neuropathy.

9. CONCLUSION

In this study, we observed that the Transcutaneous Electrical Nerve Stimulation (TENS) reduce pain & discomfort of Chronic Painful Diabetic Neuropathy. This noninvasive treatment is safe, with no side effects. It appears that such a non pharmacological modality could be useful for symptomatic relief and offers a potential treatment option.

10. LIMITATIONS

In this study, we observed that the Transcutaneous Electrical Nerve Stimulation (TENS) reduce pain & discomfort of Chronic Painful Diabetic Neuropathy. This noninvasive treatment is safe, with no side effects. It appears that such a non pharmacological modality could be useful for symptomatic relief and offers a potential treatment option.

11. RECOMMENDATIONS

- Follow up study
- Include more scale for outcome measures .(Functional outcome measures)
- Compare the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) on chronic painful Diabetic Neuropathy (PDN) between type I & II Diabetic Mellitus.
- Effectiveness of different electro stimulatory parameters may remain investigated

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