International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Index Copernicus Value (2016): 79.57 | Impact Factor (2017): 7.296

Post-Therapeutic Early Effect of External Electric Muscle Stimulation on Reduction of pain in Patients with Type-2 Diabetes and Symptomatic Peripheral Neuropathy

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Abstract: ***Aim: To find Post-therapeutic early effect of External Electric Muscle Stimulation on reduction of pain in patients with Type-2 diabetes and symptomatic peripheral neuropathy. Methods: The Participants were then randomly allocated into Group A (Experimental group) & Group B (Control group) by using lottery system. Thirty participants were assigned in each group. Group A (n= 30) received external EMS plus aerobic exercises as home exercise program and followed a prescribed diabetic diet pattern, and Group B (n= 30) received aerobic exercises as home exercise program and followed a prescribed diabetic diet pattern. Participants in the both groups were engaged in the same 40-min aerobic exercises 5 days per week for 2 weeks and were following the same diabetic diet pattern for the period. Results: Significant Results were found. Conclusion: EMS was shown to be of great benefit in type 2 diabetes patients treated depending on the definition of reduction of pain, is free of side effects, and led to an accentuated improvement in neuropathic symptoms.***

Keywords: Diabetes, Neuropathy, Electrotherapy, Physiotherapy, Pain

1. Introduction

Diabetes mellitus (DM) is probably one of the oldest diseases known to man. It was first reported in Egyptian manuscript about 3000 years ago.[1]DM, commonly referred to as diabetes, is a group of metabolic disorders in which there are high blood sugar levels over a prolonged period. Symptoms of high blood sugar include frequent urination, increased thirst, and increased hunger. If left untreated, diabetes can cause many complications. Acute complications can include diabetic ketoacidosis, hyperosmolar hyperglycemic state, or death. Serious long-term complications include cardiovascular disease, stroke, chronic kidney disease, foot ulcers, and damage to the eyes.[2] Diabetes is due to either the pancreas not producing enough insulin or the cells of the body not responding properly to the insulin produced. There are three main types of diabetes mellitus[3] - Type 1 DM results from the pancreas's failure to produce enough insulin. This form was previously referred to as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes". The cause is unknown. Type 2 DM begins with insulin resistance, a condition in which cells fail to respond to insulin properly. As the disease progresses a lack of insulin may also develop. This form was previously referred to as "non-insulin dependent diabetes mellitus" (NIDDM) or "adult-onset diabetes". The most common cause is excessive body weight and insufficient exercise. Gestational diabetes is the third main form and occurs when pregnant women without a previous history of diabetes develop high blood sugar levels.

The incidence of DM has increased dramatically in recent decades, predominantly because of changes in life style, an increase in the prevalence of obesity and longevity. Current projections estimate that the number of people with DM has increased by 50.0% by 2010, and will nearly double by 2025.[4]

Nerve damage, which is one of the serious long-term complications of DM is the area of the interest of this study. Nerve damage caused by diabetes is also known as Diabetic Neuropathy (DN). Diabetic neuropathy occurs because of complex interaction between hyperglycemia-induced metabolic and biochemical changes and inadequate perfusion pertaining to micro-vascular changes. There are various forms of diabetic neuropathy: peripheral, autonomic, proximal, and focal. Diabetic Peripheral Neuropathy (DPN) is the most common form of nerve damage and is estimated to be present in around half of all diabetic patients. Its incidence is 2% per year. It is worth noting that most of the patients do not volunteer symptoms, and it is not uncommon to accidently uncover abnormal neurology during regular clinical examination. Its onset is insidious and if allowed to progress the condition will become chronic

2. Methodology

Seventy-two Type 2 diabetes patients with symptomatic diabetic peripheral neuropathy who were aged >40 years and had HbA1c levels <11% were enrolled in the present study after obtaining written informed consent. The study protocol was approved by the Ethical Review Committee of Ayushman College, Bhopal, MP, India. Based on inclusion and exclusion criteria candidates were recruited for the research project. A detailed history of diabetes and a neurological examination of the lower extremities were performed to establish eligibility in all the candidates. Four participants were excluded from the analysis due to presence of other complications. Eight participants dropped out from the research project. Remaining sixty participants were then

randomly allocated into Group A (Experimental group) & Group B (Control group) by using lottery system. Thirty participants were assigned in each group. Group A (n= 30) received external EMS plus aerobic exercises as home exercise program and followed a prescribed diabetic diet pattern, and Group B (n= 30) received aerobic exercises as home exercise program and followed a prescribed diabetic diet pattern. Participants in the both groups were engaged in the same 40-min aerobic exercises 5 days per week for 2 weeks and were following the same diabetic diet pattern for the period. All the participants of both the groups were also under insulin therapy/oral medications to control their blood glucose level.

3. Results

Results concluded statistically that the participants intervened with EMS, aerobic exercises and diabetic diet pattern had significant improvement in pain (P=0.0000) and NSS Score (P=0.0000). Overall, research highlighted that EMS along with diabetic diet pattern and aerobic exercises may be preferred as an effective therapeutic program for reducing pain and neuropathic symptoms in Type 2 diabetic and peripheral neuropathy patients when analysed with VAS and NSS. Conclusively with all the above statements and inferences from the tables and graphs it is indicated that there is rejection of null hypothesis. Therefore, the experimental hypothesis is accepted which states that "use of external EMS in combination with aerobic exercise program and diabetic diet pattern in Type 2 Diabetes and symptomatic peripheral neuropathy patients is significantly effective in reduction of pain along with other symptoms".

Table 1: Baseline characteristics of the treated patients (Pre-test)

S. no.	Characteristics	Mean & ± SD values	
		Group A	Group B
1.	Age (years)	57.60±7.10	58.67±7.77
2.	Gender (M/F)	60%/18=M 40%/12=F	43.3%/13=M 56.7%/17=F
3.	BMI (kg/m^2)	28.99±3.36	27.01±3.^{5}0
4.	HbA1c (%)	8.31±1.26	8.00±0.79
5.	Diabetes duration (years)	15.97±6.67	14.63±6.67
6.	Visual Analogue Scores	7.63±1.03	7.80±0.80
7.	Neuropathy Symptom Scores	8.03±0.96	8.23±0.62
8.	Neuropathy Disability Scores	7. 67±1.39	7.70±0.83

* M= Male, F= Female

Table 2: Comparison of pain parameter on VAS between subjects of Group A and Group B at pre- intervention and post intervention stages

Paired T Test	Comparison			
	VAS			
	Group A		Group B	
	Pre	Post	Pre	Post
Mean	7.63	2.47	7.80	7.27
S.D.	1.033	0.900	0.805	0.980
Number	30	30	30	30
Mean Difference	5.17		0.53	
Paired T Test	20.334		5.757	
P value	0.0000		0.0000	
Table value at 0.05	2.05		2.05	
Result	Significant		Significant	

Table 3: Comparison of score on NSS between subjects of Group A and Group B at pre- intervention and post intervention stages

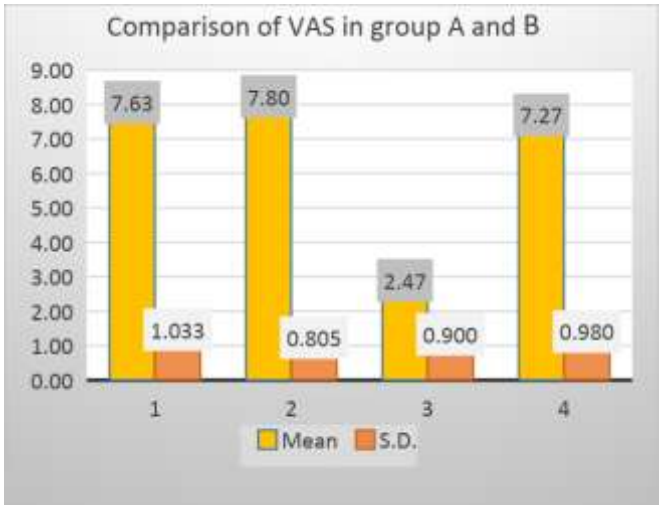
Paired T Test	Comparison			
	NSS			
	Group A		Group B	
	Pre	Post	Pre	Post
Mean	8.03	4.17	8.23	7.57
S.D.	0.964	0.950	0.626	0.679
Number	30	30	30	30
Mean Difference	3.87		0.67	
Paired T Test	25.849		7.616	
P value	0.0000		0.0000	
Table value at 0.05	2.05		2.05	
Result	Significant		Significant	

Table 4: Comparison of score on NDS between subjects of Group A and Group B at pre- intervention and post intervention stages

Paired T Test	Comparison			
	NDS			
	Group A		Group B	
	Pre	Post	Pre	Post
Mean	7.67	7.23	7.70	7.37
S.D.	1.398	1.524	0.837	0.809
Number	30	30	30	30
Mean Difference	0.43		0.33	
Paired T Test	4.709		3.808	
P value	0.0001		0.0007	
Table value at 0.05	2.05		2.05	
Result	Significant		Significant	

Table 5: Comparison using unpaired t-test for pain parameter score on VAS between subjects of Group A and Group B at pre- intervention and post intervention stages

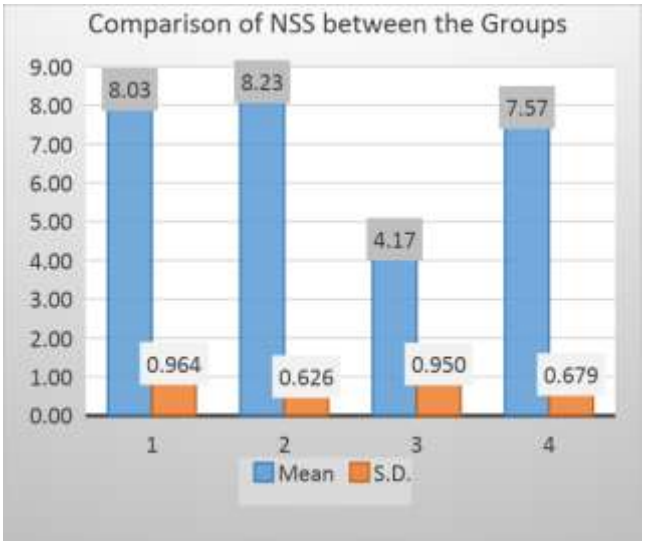
Unpaired T Test	Comparison			
	VAS			
	Pre		Post	
	Group A	Group B	Group A	Group B
Mean	7.63	7.80	2.47	7.27
S.D.	1.033	0.805	0.900	0.980
Number	30	30	30	30
Mean Difference	-0.17		-4.80	
Unpaired T Test	0.697		19.761	
P value	0.4887		0.0000	
Table Value at 0.05	2.00		2.00	
Result	Not-Significant		Significant	



Graph 1: Bar diagram depicting the distribution of the mean and standard deviation of VAS scores of the studied subjects of both groups at pre and post intervention stages using unpaired T-test

Table 6: Comparison using unpaired t-test of scores on NSS between subjects of Group A and Group B at pre-intervention and post intervention stages

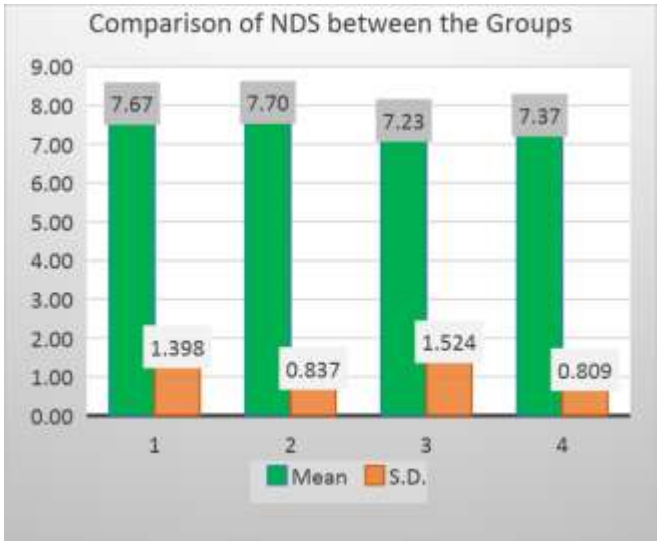
Unpaired T Test	Comparison			
	NSS			
	Pre		Post	
	Group A	Group B	Group A	Group B
Mean	8.03	8.23	4.17	7.57
S.D.	0.964	0.626	0.950	0.679
Number	30	30	30	30
Mean Difference	-0.20		-3.40	
Unpaired T Test	0.953		15.950	
P value	0.3446		0.0000	
Table Value at 0.05	2.00		2.00	
Result	Not-Significant		Significant	



Graph 2: Bar diagram depicting the distribution of the mean and standard deviation of NSS scores of the studied subjects of both groups at pre and post intervention stages using unpaired T-test.

Table 7: Comparison of score on NDS for diabetic peripheral neuropathy symptoms between subjects of Group A and Group B at pre- intervention and post intervention stages using unpaired t-test

Unpaired T Test	Comparison			
	NDS			
	Pre		Post	
	Group A	Group B	Group A	Group B
Mean	7.67	7.70	7.23	7.37
S.D.	1.398	0.837	1.524	0.809
Number	30	30	30	30
Mean Difference	-0.03		-0.13	
Unpaired T Test	0.112		0.423	
P value	0.9112		0.6737	
Table Value at 0.05	2.00		2.00	
Result	Not-Significant		Not-Significant	



Graph 3: Bar diagram depicting the distribution of the mean and standard deviation of NDS scores of the studied subjects of both groups at pre and post intervention stages using unpaired T-test.

4. Discussion

Current first study on treatment effects of combining EMS with aerobic exercises and prescribed diet pattern in a group of Type 2 diabetes patients is a recent innovation in field of research on Type 2 diabetic cases. The finding of the study (paired t-test) suggests that both the study group benefitted from the interventions with a significant improvement in pain and symptom control. Individual group analysis (unpaired t-tests) indicated that those participants receiving the combination of EMS, aerobic exercises and a prescribed diet pattern had shown better improvement than the group receiving only aerobic exercises and a prescribed diabetic diet pattern. Improved scores in the Group A participants could be as a result of the composition of the intervention they received in a specified manner i.e., under supervision for EMS and guided home exercise based aerobic exercises plan.

The data shows significant improvement of pain and other neuropathic symptoms in the participants of group A. After administration of the intervention among adults of Group A, the average scoring (Mean ± Standard Deviation) of individual of (2.47±0.900 points) measured on VAS found

to be significantly greater at post-intervention stage as compared to average scoring of participants of Group B (7.27±0.980 points). These adequate differences in scoring (-4.80 points) on VAS at post-intervention sampling stage between Group A and Group B could reach at statistically significant ($p<0.05$) level of significance. Similarly, after administration of the intervention among adults of Group A, the average scoring (Mean ± Standard Deviation) of individual of (4.17±0.950 points) measured on NSS found to be significantly greater at post-intervention stage as compared to average scoring of participants of Group B (7.57±0.679 points). These adequate differences in scoring (-3.40 points) on NSS at post-intervention sampling stage between Group A and Group B reached at statistically significant ($p<0.05$) level of significance.

But, after administration of the intervention among adults of Group A, the average scoring (Mean ± Standard Deviation) of individual of (7.23±1.524 points) measured on NDS found to be insignificant at post-intervention stage as compared to average scoring of adults of Group B (7.37±0.809 points). These adequate differences in scoring (-0.13 points) on NDS at post-intervention sampling stage between Group A and Group B did not reach at statistically significant ($p<0.05$) level of significance. Moreover, this was concluded statistically that adults of Group A and B intervened with different treatment protocols could not be infered using NDS, which shows non-significant relationship in control of symptoms when analyzed using NDS.

The reduction in pain and neuropathic symptoms can be considered a strong and clinically relevant improvement. Statistical analyses revealed that response to treatment was independently and positively associated with the NSS and VAS, but not with the NDS. This suggests that Type 2 diabetes patients at all ages and stages of disease might benefit from EMS. Additional metabolic factors such as BMI or even HbA1c, as a marker of long-term glucose control, did not influence the response rate significantly. Pain and neuropathic symptoms in our study were reduced by -4.80 and -3.40, respectively, that can also be considered clinically relevant. Our data support the previously published high response rates of EMS in pilot studies and patients with symptomatic diabetic and uremic neuropathy byBeata Strempska et. al.[5] The underlying reasons for this large variation remain unclear, and it seems important to decipher the physiological changes induced by EMS to understand this finding. According to Reichstein and co-authors, EMS treatment has been reported to be an effective treatment to alleviate symptoms of DN.[6-8] In current study, it is reported that electrical stimulation reduces pain through nociceptive inhibition at the pre-synaptic level in the dorsal horn. This limits central transmission of pain signals. Large-diameter fibers are thought to be activated by high-frequency electrical stimulation.[9]

Although not an endpoint of this study, it seems likely that for example the significant reduction of pain reported by the participants leads to a mild improvement in other associated neuropathic symptoms too. This improvement and the absence of severe adverse effects seem to be reflected by the strong adherence to the study protocol over a period of 2 weeks and eight treatment sessions as none of the participants reported any kind of chemical or electrolytic burns or ulcers. Future controlled studies will be needed to study cost-effectiveness and clinical efficacy of EMS in comparison to pharmaceutical interventions, especially in consideration of other missing relevant side effects.

5. Conclusion

EMS was shown to be of great benefit in type 2 diabetes patients treated depending on the definition of reduction of pain, is free of side effects, and led to an accentuated improvement in neuropathic symptoms. Both the Groups A & B are showing significant difference for post intervention but on statistical analysis of mean differences Group A is statistically more significant compared to Group Morecontrolled trials will be needed in future to clearly define the clinical and economic efficacy of this treatment option

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