The Impact of High Tone Power Therapy on Pain and Functional Abilities of Diabetic Patients with Lumbar Radiculopathy

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Abstract

Background: the sector of electro therapy grows rapidly recently; high tone power therapy (HTT) may be a new modality in this field with a primary aim directing towards its effect on the cellular metabolism. This work aimed to check the effect of high tone power therapy on functional ability and pain in diabetic patients with lumbar radiculopathy. **Methodology:** sixty diabetic patients type II were randomly classified into two groups equally in number (control & study groups): group B (control) received selected designed program of therapy for 12 sessions every other day for four weeks, each session for 0.45 hour while group A (study) received high tone power therapy plus the same program of physiotherapy as control group for 12 sessions every other day, for four weeks, each session lasted for 1.45 hours, one hour for HTT and 45 min for selected designed physiotherapy program. Patients were assessed neurophysiologically by: (H-Reflex latency and amplitude study) through using NIHON KOHDEN, JAPAN, MEB-9200/9300 measuring device and by Oswestry Disability Index (ODI) for functional outcome and by Visual analogue scale (VAS) for pain intensity. **Results:** This study revealed that neurophysiological measures were improved significantly in study group but not significantly improved in control group. Oswestry Disability Index (Functional outcome) was improved significantly in both groups with higher improvement results for study group and pain was improved significantly in both groups. **Conclusion:** HTT can be included as a valuable, effective and non-invasive method for enhancing neurophysiological, pain and functional abilities of patients with type II diabetes.

KeyWords: High tone power therapy; Neurophysiological measures: H-Reflex latency and amplitude; Functional abilities; Diabetic patients with lumbar radiculopathy.

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Introduction

Diabetic polyneuropathies (DPN) is defined as peripheral nerve dysfunction. Diabetic neuropathy defines various types of nerve destruction considered with diabetes mellitus. The nerve damage site controls symptoms and may include weakness as motor changes; sensory symptoms such as tingling, numbness, or pain; or urinary symptoms as example of autonomic changes.

Micro vascular injury affecting small blood vessels that supply nerves (vasa nervosa) may be responsible for these changes. Many conditions may be associated with diabetic neuropathy including distal symmetric polyneuropathy, mononeuropathy; mononeuropathy multiplex; diabetic amyotrophy, third, fourth, or sixth cranial nerve palsy; and autonomic neuropathy **(Lu et al., 2020).**

The pathologic changes of Diabetic polyneuropathies involve three main alterations: inflammation, oxidative stress, and mitochondrial dysfunction. Diabetic distal symmetrical sensory polyneuropathies (DSP) account for 20–30% of the type 2 diabetic population in hospitals and 20% of diabetic samples taken from the general public **(Iqbal et al., 2018).**

One can categorize Neuropathic symptoms as being negative or positive, based on decreased responsiveness to stimuli or spontaneous sensory symptoms respectively. Positive sensory symptoms come in a wide variety, and it has been suggested that they can be divided into groups for painful and non-painful symptoms. Antidepressants, tricyclics, analgesics, and anticonvulsants are sometimes the only medications that can help these people with their discomfort and agony because the etiology of DSP in humans is poorly understood **(Preston and Shapiro, 2013).**

A published meta-analysis highlighted a proof that using α-lipoid acid in treatment improves neuropathic deficits and positive neuropathic symptoms in DSP. percutaneous electrical nerve stimulation, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation, acupuncture and other physical therapies modalities have been successfully used as non-pharmacological therapies, **(Oh, 2020).**

Lumbar radiculopathy in diabetic people is more common and is regarded as the main cause of disability globally. Lumbar radiculopathy in diabetic people includes a variety of different diseases. Each of these ailments has a high prevalence, is frequently characterised by recurrence, and poses a significant public health burden. Persistent musculoskeletal low back pain, chronic lumbosacral radicular pain (such as sciatica), and claudication in neurological patients with lumbar spinal stenosis are the three main diagnostic diagnoses. These three illnesses are paradigmatic and each has a distinct treatment approach, epidemiology, and potential neurological underpinnings **(Lu et al., 2020).**

Chronic low back pain (LBP) is one of the most common types of back pain and is found in about 60–80% of people at certain time in their lives. One characteristic of LBP in adolescence is its liability to reappear with high recurrence and greater intensity. The intensity is usually low and it generally lasts for less than a week, LBP causes reduction or ceasing of physical activity and limitations in carrying out activities **(Muresanu et al., 2020).** Low back problems may radiate to the lower limb (s). Sciatica true prevalence is approximately two to five percent while leg pain prevalence associated with back pain, is approximately 35% **(Martini et al, 2021).**

High tone therapy device is a new device with a unique characteristics of electrotherapy and its main effects for the body are entering energy into the body to revitalize the body and to affect and stimulate cells and inducing a resonance effect that makes vibration or an oscillation in the tissues and cells in order to relieve pain, enhance metabolism and distributing the pain mediators and inflammation, waste substances and nutrients; thus normalizing the cell and organizing metabolism and nerve regeneration **(Ogrodzka-Ciechanowicz et al., 2020).**

In comparison to classical electrotherapy (transcutaneous electrical nerve stimulation TENS and low frequency currents), High tone power therapy works with medium-frequency, alternating current, whose amplitude is simultaneously modulated and whose frequency oscillates between 4.000 Hz and 33.000 Hz. HTT stimulates different tissues by using alternating electric fields. HTT transmits much energy through skin surface electrodes to tissues. Moreover; the current frequency and intensity can be modulated at the same time **(Spanidis et al., 2016).**

Materials&Methods

Subjects:

Sixty controlled (HBA1C ≤ 6.4) according to Román-Pintos et al., (2016) diabetic patients type II for more than 10 years duration, from both genders, The patient's age ranged from 40 to 55 years old **(Muresanu et al., 2020)**, diagnosed and referred with lumbar radiculopathy from a neurologist with MRI of the lumbosacral spine that revealed unilateral

lumbar radiculopathy. Diabetic type II patients were endorsed from the neurology outpatient clinic, Faculty of Physical Therapy, Cairo University. Patients were divided randomly into two groups who were matched and equal in number.

Study Group (A): included 30 diabetic patients with lumbar radiculopathy who received HTT plus Selected designed physiotherapy program: (a 10-minute pulsed ultrasound on the paraspinal area of the lumbar spine Exercises that improve range of motion include active range of motion (AROM), wobble board training, light manual stretching for both LL and graduated gait training) for 12 sessions 3 times per week for four weeks, the session lasted for 1.45 hours. One hour for High tone power therapy and 45 min for a selected designed physical therapy program.

Control Group(B): included 30 diabetic patients with lumbar radiculopathy and treated with the same protocol of selected designed physiotherapy program only for 12 sessions, three sessions per week for four weeks, the session lasted for 45 minutes.

Randomization:

The control group (B) and study group (A) were randomly allocated to 60 diabetic individuals with lumbar radiculopathy. The use of sealed, sequentially numbered, opaque envelopes allowed for concealed allocation. An author who was not involved in data collection created the randomization. The therapy was then carried out in accordance with group assignment after one author opened the envelope. An author who was blinded to group allocation collected data at baseline and after the three-month period had ended.

- Blinding

All patients were assessed by the same physician before the beginning of physical therapy and at the end of treatment. Neither the investigator nor the patients were informed of the treatment assignments and allocation.

-Ethical Committee

The protocol was accepted by the Cairo University **P.T.REC/012/003608**Physical Therapy Research Ethical Committee on February 27, 2022.

- Inclusive criteria

All patients were controlled (HBA1C ≤ 6.4) type II diabetes not less than 10 years duration for diabetes [examined according to protocol of H reflex, general clinical evaluation sheet and specific for lumbar radiculopathy]. All patients were treated by the following medications only; oral hypoglycemic drugs, Analgesics: eterocoxib (pain clear) Vitamin B12: Milga. Age: ranged from 40 to 55 years **(Martini et al., 2021).** All patients' body mass indices (BMIs) varied from 20 to 25 kg/m^2. All of the individuals who were chosen for this study had lumbar radiculopathy referred from neurologist with H reflex study and MRI. Patients had painful lumbar movement, pain and paresthesia in at least one nerve root distribution. Patients were medically stable and with medical diabetic control. All patients were ambulatory independently. Patients approved signing a consent form.

- *Exclusive Criteria*

Exclusion of the patients were done if they had: history of lumbar canal stenosis, history of lumbar spine surgery, diagnosis of lumbar myelopathy, had received pain treatment within the three months prior to the research, disorders include multiple sclerosis and persistent infections, rheumatologic ailments like severe lumbar spine degenerative disease, polyarticular osteoarthritis, rheumatoid arthritis, and mild systemic lupus erythematosus, birth defects or space occupying lesions, issues with structural integrity and osteoporosis.

Instrumentation

- *Evaluative tools and equipment:*

Both general and specific neurological evaluation sheet: Patients were clinically examined at base line before and after treatment program using general and specific neurological sheet. Weight and height scale: was used for measuring the weight and height of all patients before starting the assessment for determining BMI. A visual analogue scale was used to evaluate the degree of pain (VAS). Assessment of functional disability: by Oswestry Disability Index (ODI). Neurophysiologic study: (H-Reflex latency and amplitude study); was assessed in EMG lab at Faculty of Physical Therapy, Cairo University.

- *Therapeutic tools and equipment*

1-High Tone Power Therapy

(HiTop 191; gbo Medizin technik, Rimbach, Germany MODEL: 191, 2021). It is a microprocessor-controlled for electrotherapy. The frequency range employed spans three octaves, or 4096 Hz to 32768 Hz. It uses medium frequency sine waves to operate. There are no DC elements in the treatment. It consists of: (1) Box for accessories. (2) Display. (3) Main switch. (4) Intensity and modification regulator. (5) Output plug for connector to the patient cable.

2-Selected designed physical therapy program.

- *Therapeutic Procedure:*

Selected and designed physical therapy program: was done for study and control groups: Both groups were exposed to a selected and designed physical therapy program. It consisted of the following: **(Ammendolia et al., 2022).** In the lumbar region's paraspinal area, electrotherapy used pulsed ultrasound for 10 minutes paraspinal. Training with a wobbling board: The patient will stand on a round, then squared, wobble board that will move between parallel bars while being supported by hands in front of a mirror. Patients will stand on a wobble board that has been circular and then squared and will travel between parallel bars in front of a mirror without any hand support. Exercises for active range of motion (AROM): Active back strengthening **(Ammendolia et al., 2022).** The patient will be instructed to perform the exercises with repetition 10 times for every movement. Active free dorsiflexion and plantar flexion of the ankle joint, active free flexion and extension of the knee and active free flexion and extension of the hip joint against gravity, holding each direction for ten seconds (secs).

Exercises to develop the deep abdominal muscles, as well as the oblique abdominal, multifidus, quadratus lumborum, and erector spinae muscles, in order to promote isolated spinal stabilization (e.g., transversus abdominus**) (Aneis and Al-Azab, 2017),** Gentle manual stretching exercises for LL: iliopsoas, Hamstring, and calf muscles most commonly tight in LL. Graduated gait training: The patient will walk within parallel bars; with then without hand support in front of mirror. The patient will walk and pass obstacles; with then without hand support in front of mirror **(Colberg et al., 2010).**

2-High tone power therapy:

External muscle stimulation was carried out using a non-portable 230-V power supply equipment **(HiTop 191-H; gbo Medizin technik, Rimbach, Germany)** that generates pulse widths of roughly 350 mA, 70 V, and an initial frequency of 4,096 Hz. After three seconds, the maximum frequency was down modulated from 32,768 to 4,096 Hz.

Each patient's amount of electrical stimulation was adjusted to a nice level that didn't cause any pain or bothersome paresthesia. HiToP 191-H uses medium frequency sine waves for therapy from a technological perspective. There are no direct current (DC) components in the therapy. The trained muscles are strongly stimulated by tetanic contraction when the patient's electro-sensitive threshold curve is crossed by 20 Hz (typically: 3 seconds ramp - 3 seconds stimulation - 3 seconds pause). The frequency and amplitude of the carrier wave are simultaneously modulated. SimulFAM, which stands for simultaneous frequency amplitude modulation, is a technique that scans the therapeutic frequency with a predetermined frequency **(Strempska et al., 2013).**The location of the electrodes was on the lumbar region paraspinal. **(Strempska et al., 2013).**

Results

I. All demographic features of the patients in both Group (A) and Group (B) are illustrated in table (1).

The mean values were compared and revealed that there was non-significant difference between GA and GB regarding age, height, weight and BMI between the both groups. t- value for age was 0.31 at P= 0. 756. t- value for height was 0.21 at P= 0. 838. t- value for weight was 1.83 at P= 0.083. t- Value for BMI was 0.17 at P= 0.833 table (1).

- *Pretreatment comparison:*

Visual Analogue Scale mean value for groups A and B pre treatment were 71.0 ± 13.7 and 70.7 ± 10.8 respectively, t- value for Visual Analogue Scale pre treatment was 0.09 at P= 0.925. The mean value for Oswestry Disability Index (ODI) pre treatment for groups A (Study group) and B (Control group) were 19.87 ± 4.22 and 19.77 ± 4.17 respectively, t- value for Oswestry Disability Index (ODI) pre treatment was 0.09 at P= 0.927. The mean value for The H-reflex latency test pre treatment for groups A (Study group) and B (Control group) were 32.11 ± 0.885 and 31.81 ±0.86 (msec.) respectively, t- value for H-reflex latency test pre treatment was 1.31 at P= 0.195. The mean value for the H-reflex amplitude test pre treatment for groups A (Study group) and B (Control group) were 3.11 ± 0.53 and 3.08 ± 0.42 (μv) respectively, t- value for H-reflex amplitude test pre treatment was 0.76 at P= 0.392.

The results illustrate that all patients in both groups pre treatment were matched and equal to each other to be able to show the effects and changes in parameters post application of treatment methods.

Comparison of the mean values of Oswestry Disability Index (ODI) Scale and Visual Analogue Scale (VAS) in both groups before and after treatment: are illustrated in table (2).Comparison of the mean values of the H-reflex Latency and Amplitude tests in both groups before and after treatment: are illustrated in table (3).Comparison of the mean values of Visual Analogue Scale (VAS), Oswestry Disability Index

(ODI) and the H-reflex test of the patients in both groups after treatment illustrated in table (4).

Table 1. Mean values of general characteristics in both groups.

Item	Study (GA)	Control (GB)	t-value	*p* value
	Mean ±SD	Mean ±S D		
1- Age (years)	51.76 ±4.43	51.46 ±4.51	0.31	0.756
2- Height (Cm.)	163.80 ±5.53	163.50 ± 4.41	0.21	0.838
3- Weight (Kg.)	84.25 ±7.89	87.50 ± 7.87	1.83	0.083
4-BMI/ (Kg/m^2)	26.83± 2.36	27.21± 2.45	0.17	0.833

Table 2. Comparison of the mean values of Visual Analogue Scale (VAS), Oswestry Disability Index (ODI) Scale in both groups before and after treatment.

Results	Oswestry Disability Index (ODI)				Visual Analogue Scale			
	GA		GB		*GA*		GB	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Mean ± SD	19.8 ± 4.2	8.7 ± 5.9	19.7 ± 4.1	18.1 ± 4.1	70.9±13.6	26.0±12.7	70.7 ±10.8	65.1 ±11.2
Median	19.5	8.5	20	17.5	70.0	23.0	67.00	62.0
Minimum	12.0	1.0	12	11.0	40	10	50	41
Maximum	24.0	21.0	24	24	99.0	53	97	92
Statistical t-value	5.33		3.39		17.48		6.89	
p value post	0.000**		0.002*		0.000**		0.000**	

Table 3. Comparison of the mean values of the H-reflex Latency and Amplitude tests in both groups before and after treatment.

Descriptive results	The H-reflex Latency (msec.)				The H-reflex Amplitude (µV)			
	GA		GB		GA		GB	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Mean ± SD	32.1 ± 0.88	31.0 ± 0.88	32.1 ± 0.89	31.7 ± 0.92	3.1 ± 0.53	4.1 ± 0.8	3.0 ± 0.4	3.4 ± 0.5
Median	31.9	30.8	31.9	31.5	3.12	4.1	3.10	3.5
Minimum	30.7	29.7	30.7	29.9	2.9	3.4	2.8	3.2
Maximum	33.5	32.7	33.5	33.4	3.75	4.4	3.7	3.9
Statistical t-value	10.74		1.68		6.55		1.09	
p value post	0.000**		0.103		0.002*		0.038*	

Table 4. Comparison of the mean values of Visual Analogue Scale (VAS), Oswestry Disability Index (ODI) and the H-reflex test of the patients in both groups after treatment.

	Study (GA)	Control (GB)	t-value	p- value
	Mean ±SD	Mean ±SD		
1- Visual Analogue Scale (VAS)	26.0 ± 12.8	65.1 ± 11.3	-12.57	0.000**
2-Oswestry Disability Index (ODI)	8.73 ± 5.97	18.20 ±4.02	-7.21	0.000**
3- The H-reflex latency (msec.)	31.05± 0.88	31.74 ±0.92	-2.95	0.005**
4.The H-reflex amplitude (µv)	4.12 ± 0.87	3.40 ± 0.53	2.17	0.036*

SD: standard deviation; **P > 0.05 =** Non-significant; **P ≤ 0.05 =** significant*; **P ≤ 0.01 =** highly significant*

Discussion

The goal of the current study was to determine how high tone power (HiTop) therapy affected patients with lumbar radiculopathy who were diabetic and had poor clinical, pain, and functional outcomes.

Being the first to examine how HiTop therapy affects clinical, pain, and functional outcomes in diabetic patients with lumbar radiculopathy, the current study is special. While several types of treatment are used for diabetic people with lumbar radiculopathy, there is lack of evidence that they are effective. Interferential treatment, TENS, classical exercise therapy, Proprioceptive neuromuscular facilitation techniques (PNF), and recently the new scope of high tone power (HiTop) therapy are all recommended for diabetic individuals with lumbar radiculopathy **(Tagliaferri et al, 2020).**

The results of this study showed that 1) there was a clinically and statistically significant improvement in neurophysiological measures in the study group that underwent high-tone power therapy along with a chosen physical therapy programme; (H-reflex latency and amplitude). 2) A clinically and statistically significant improvement in the Oswestry Disability Index (Functional outcome) in both groups following therapy, with the study group improving more than the control group in this regard.

Many reports specifically evaluated the effectiveness of different treatment modalities on LBP and sciatica subjects, but there is very little literature regarding the use of high tone power therapy (HTT) in the management of LBP in diabetic patients with lumbar radiculopathy; this is because diabetic radiculopathy pain is typically more resistant to treatments than radiculopathy pain alone.

The current study's findings may be explained by **Rose et al., (2008),** who confirmed that treatment with high tone power therapy has beneficial effects on improving glycemic control, body weight, promotes exercise capacity, and improves function performance in patients with diabetes type two. Patients with type II diabetes who are has a low exercise capacity may benefit from high-tone power therapy as an extra therapeutic option.

Klassen et al. (2013) proposed that high-tone power therapy can relieve the discomfort, pain, and impaired function associated with diabetic patients with lumbar radiculopathy, and that it could be a useful supplement in the alleviation of their impaired function, pain, and neuropathic discomfort.

Peckova et al. (2012) stated that the data demonstrated for the first time that treatment with

high tone power therapy can raise glomerular filtration rate, cell metabolism, mitochondrial size, and the balance between cell catabolism and anabolism, resulting in improvements in all body functions.

Nowakowska et al. (2009) observed that high-tone power therapy increased the blood flow dynamics in peripheral microcirculation, increased tissue perfusion, and improved cell and all-body function capability, which may explain the current study's findings. As a result, as shown in their study, high-tone power therapy may be a useful instrument in solving problems of the peripheral blood circulation (such as diabetic neuropathy).

A clinically and statistically significant improvement in the Oswestry Disability Index (Functional outcome) in both groups post-treatment, with the study group improving more than the control group in comparison to pre-treatment mean values, and this can be explained by the fact that high tone power therapy (electrodes placed on the lumbosacral region and affecting all body systems) improves all body cell metabolism, nerve regeneration, and endogenous opioid production **(Robinson, 2008).** It also improves microcirculation and endoneurial blood flow by increasing vasodilation (increased nitric oxide bioavailability) (locally and systemically). Furthermore, suppression of sympathetic afferent activity is thought to reduce transmission of pain to the brain. Another assumption is that the quantity and size of mitochondria will increase, as will the diffusion rate and the rate of diffusion **(Robinson, 2008).**

The current study results came in agreement with **Mohamed, (2017)** who revealed that high tone power therapy bares an increased potential for short term reduction of peripheral radicular lower limb pain and improvement of lower limb function performance than TENS and might offer new therapeutic window for improved function. High tone power therapy may offer new therapeutic strategies for improved function than TENS. Function improvement was indicated by 56 percent of subjects after HiTop and 41 percent after TENS.

Klassen et al. (2013) validated and agreed with the current findings of the performed study, showing a statistically significant increase in functional outcome, quality of life, and physical health in patients with peripheral neuropathy after treatment with high-tone power therapy. Twenty-five patients (8 women /17 men, average age 62.2 14.2 years) were included in the study and the measurement of quality of life parameters through questionnaires.

The results of the present study are in contrast to those of **Ogrodzka-Ciechanowicz et al. (2020),** whose analysis revealed that there were no statistically significant differences between the high-tone power therapy group and the control group when measuring the maximum muscle torque of the knee extensors. In their studied variables, the investigation did not reveal any statistically significant differences. They came to the conclusion that high tone power therapy, which is used to treat patients who have had their anterior cruciate ligaments (ACL) repaired, had no discoverable impact on the quadriceps muscle's strength or the operation of the knee joint. However, the conclusions drawn from their studies remain murky. One possible reason for this discrepancy is the low frequency of treatments during the week, which range from 3 days per week for the first 3 months to 2 times per week for the following 3 months. The way that patients approach and behave during physical therapy is another factor. Unfortunately, a lot of individuals believe that after receiving electro stimulation, they must exercise excessively vigorously or at home. Patients who did not receive extra therapy had higher exercise motivation. A mindset like that might lead to negligible variations between the Groups. Both Groups received the same treatment and rehabilitation, however the outcomes were extremely similar and all patients met their objectives. Because of this, even proper treatment and rehabilitation might have positive results.

The investigator attempted to validate the introduction of high tone power (HiTop) therapy as one of many electrotherapeutic modalities associated with rehabilitative approaches used in the management of lumbar radiculopathy in diabetic patients, using disability data and pain assessment, as well as an objective way to prove such improvement, H-reflex latency and amplitude.

The current study's findings imply that adding high-tone power therapy is more beneficial than chosen selected physical therapy program alone in improving and enhancing functional outcomes and pain in diabetic patients with lumbar radiculopathy. The current study's teamwork reveals that high-tone power therapy is a cheap, useful, effective, and non-invasive therapeutic option for diabetic patients with lumbar radiculopathy. The current study's team believes that all physical therapy programmes for

diabetic individuals with lumbar radiculopathy will include high-tone power therapy in the future.

Limitation of the study:

The current study was limited by the following:

1- Some patients might not follow the instructions accurately during assessment and treatment.

2- Some patients fear from pain during assessment and treatment.

3- Some patients refused to be transported to different places during assessment and treatment and some patients travelled to another city.

4- Changes of patient's lifestyle and educational level.

5- Motivations difference between all patients.

Conflictofinterest

Allauthorsstatednoconflictofinterests.

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