

## RESEARCH REPORT

# EFFECTIVENESS OF HIGH FREQUENCY TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AT THE TENDER POINT OF UPPER CERVICAL AS ADJUNCTIVE THERAPY OF FIBROMYALGIA PATIENTS

## ABSTRACT

### OBJECTIVES

Evaluate the effectiveness of high frequency transcutaneous electrical nerve stimulation at the tender point of upper cervical as adjunctive therapy of fibromyalgia patients.

### STUDY DESIGN

It is a randomized control trial study design

### STUDY SETTINGS & PARTICIPANTS

The study was conducted on 30 participants with the age group of 20-65 years upon females with clinically diagnosed condition of fibromyalgia in tertiary health care centre.

### METHODS

In this study, all the participants were divided in to two groups, group 1 (N=15) and group 2 (N=15). Group 1 (N=15), received TENS with exercise therapy and group 2 (N=15), received only exercise therapy. Both the groups received 4 sessions per week and in whole the participants were attended 32 sessions in eight weeks of duration.

### RESULT

TENS with exercise group 1 (N=15) had a greater pain reduction ( $6.0 \pm 1.13$ ) compared with only exercise group 2 (N=15) ( $6.2 \pm 1.1$ ). There was no such huge difference between both the treatments program, but group 1 shows more improvement in the pain reduction, work performance, stiffness, fatigue, anxiety, and depression.

### CONCLUSION

Both the groups demonstrate significant results in pain reduction, stiffness, fatigued, anxiety, work performance, and depression.

### KEY WORDS

High Frequency Transcutaneous Nerve Electrical Stimulation, Fibromyalgia, Exercise Therapy, Tender Point, Pain, Cervical

### Sania Hassan Ali

Senior Lecturer  
Ziauddin College of Physical Therapy  
Ziauddin University  
sania\_hassanali@yahoo.com

### Syeda Amool Sakeena Rizvi

Lecturer  
Ziauddin College of Physical Therapy  
Ziauddin University  
sakeenarizvi5@gmail.com

### Muhammad Usman Khan

Senior Lecturer  
Ziauddin College of Physical Therapy  
Ziauddin University  
m\_khanusman@hotmail.com

[Ali SH, Rizvi SAS, Khan MU. Effectiveness of high frequency transcutaneous electrical nerve stimulation at the tender point of upper cervical as adjunctive therapy of fibromyalgia patients. Pak. j. rehabil. 2014;3(1):29-33]

## INTRODUCTION

Traditionally, fibromyalgia was frequently termed as fibrositis and categorized as an inflammatory musculoskeletal disease. Fibromyalgia (FM) is a common painful rheumatic syndrome associated with tender points, sleep disturbance, chronic fatigue, headache, anxiety, depression, and bowel symptoms<sup>1</sup>.

Fibromyalgia is the second most common disorder observed by rheumatologists after osteoarthritis. In 1990, American College of Rheumatology (ACR) classification criteria for the diagnosis of fibromyalgia required an essential tenderness on pressure (tender points) in at least 11 of 18 specified sites and the presence of extensive pain for analysis but the proper diagnosis in the recent probable changes to these investigative criteria has included the implementation of the Wide spread Pain Index (WPI) and the Symptom Severity (SS) index to enhancement the prior 'tender point' criteria. Furthermore, the healthy professional typically a Rheumatologist, will eliminate other circumstances first and then if Fibromyalgia is assumed, conduct the tender point, WPI and SS tests. Even more evidences provided occurrence of Fibromyalgia, that is, about 2% in the United States, including 3.4% of women and 0.5% of men<sup>2,3</sup>. So, according to these statistics the fibromyalgia is familiar in women as compared to the men.

Silvia et al stated in the study that, there is an association of sleep disturbance, anxiety, and overall physical functional activities<sup>4</sup>. The study accomplished that disturbed sleep increases pain, worsens physical functioning and worse physical functioning increases depression. This indicates that other relationships between symptoms exists such as, pain interfering with sleep, lack of sleep resulting in anxiety and increased pain and anxiety interfering with sleep<sup>5</sup>. The American College of Rheumatology defines fibromyalgia criteria to include pain of at least three months duration above and below the waist bilaterally, axial skeletal pain, and 11 of 18 discrete tender points<sup>6</sup>. Another authors conformed in the studies that, the environmental triggers including, physical trauma and psychosocial stressors, may be involved in the pathophysiology of fibromyalgia<sup>7,8</sup>.

Therefore, living well with fibromyalgia – the valuable approach is self-management strategies that includes regular exercise; such as, yoga or stretching exercise, medications, eating a healthy and balanced diet, relaxation exercises (breathing or aerobic exercises) and good sleep<sup>9</sup>.

Furthermore, recent studies recommended that, the treatment of fibromyalgia patients is based upon the interdisciplinary approach<sup>10</sup>, with physical therapy, pharmacological, cognitive behavioral and educational interventions. Eventually, the use of yoga in the management of fibromyalgia is essential<sup>5</sup>. In the field of physical intervention, physical therapy offers a great variety of therapeutic modalities and exercises that can be used to deal with fibromyalgia<sup>11</sup>.

Pain is constant and a key symptom of fibromyalgia for which exercise is generally endorsed, but can sometimes induce pain. The frequent treatment for musculoskeletal pain is transcutaneous Electrical Nerve Stimulation (TENS). Davis<sup>11</sup> and Okonkwo et al<sup>12</sup>, independently found evidence about inducing negative mood and stress exposure could worsen pain ratings in patients with

fibromyalgia. TENS is an electrotherapeutic method used for pain management that has been examined in the medical journalism since its inception by Wall and Sweet in 1967<sup>13</sup>.

TENS may differentially affect a multiplicity of outcomes related to pain. Pollster having expertise in clinical pain research, proposed guidelines for the measurement of pain treatment outcomes beneath Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) that focuses on foundation outcome domains, such as, pain, physical function, emotional function, comprehensive improvement, symptoms and unsympathetic effects<sup>14</sup>.

In a clinical trial, patients with neuropathic pain, TENS reduces allodynia when compared with a placebo intervention. Similarly, patients with fibromyalgia and osteoarthritis, deep tissue hyperalgesia (pressure pain threshold measure) were also reduced<sup>15</sup>.

In other words, Transcutaneous electrical nerve stimulation is an electro physical agent, capable of inducing electro analgesia by means of pulsed electrical current delivered over the skin surface<sup>16</sup>. This definition is consistent with the historical association in the scientific and clinical literature between the terms transcutaneous electrical nerve stimulation and pain management, because the use of Transcutaneous electrical nerve stimulation therapy is fundamentally for the management of pain. Pain is by far the dominating symptom that prompts people to consult health-care practitioners. The medical approach to pain therapy is to offer drugs and if drugs are not successful, then surgery is usually taken into consideration<sup>17</sup>.

Transcutaneous electrical nerve stimulation (TENS) is often used for the treatment of pain. The low frequency, high-intensity TENS activates Aa and C fibers via the recruitment of descending inhibition mechanism. Low frequency TENS (<10Hz) seems to induce analgesia by inhibiting pain transmission through mu-opioid receptors at the spinal and supra spinal levels and it is more generally used for the treatment of chronic pain. Whereas, the high-frequency TENS present as the main mechanism of action for pain, relief by the gate control theory<sup>18</sup>. Furthermore, few clinical investigate application of high-frequency TENS in fibromyalgia hence its worth must be superiorly defined<sup>15,19</sup>.

In combination of electrotherapy, exercises play an important role. In the year 1988, various studies were published, claiming that the moderate-intensity to high-intensity aerobic exercise by approach of cycling and whole-body exercise for patients with fibromyalgia, the effects of moderate-intensity to high-intensity ergo meter cycling, found that the improvements in aerobic capacity, tender point pain threshold in the group that exercised three times a week for 20 weeks<sup>19</sup>.

Additionally, the objective of the study is to investigate the efficiency of high frequency TENS at the tender point (upper cervical) at the adjunctive therapy in fibromyalgia patients

## MATERIAL AND METHOD

### Study Population and Duration

The time period of the study was 6 months, carried out in a tertiary care center, on females, ranging age between

35-65 years being diagnosed with fibromyalgia.

### Study Design and Sample Size

It is an experimental study conducted on 30 participants with the present condition of fibromyalgia. All the participants were divided into two groups, group 1 (N=15) and group 2 (N=15).

### Sampling Technique

Data were collected by using simple random sampling technique.

### Data Collecting Tool:

Tools were Assessment Form and Visual Analogue Scale (VAS).

### Inclusive Criteria

Participants included females with the age bracket of 35-65 years, with clinically diagnosed condition of fibromyalgia, attending at tertiary care center. Informed consent forms were provided by all patients and the study was approved by the ethics committee.

### Exclusive Criteria

The exclusion criteria of this study were males and those who were suffering from neurological deficit, fractures, recent surgery, and cardiovascular diseases. Additionally, any person with the history of pacemaker, seizure or chronic disorders was also excluded from this study.

### Procedure

The data was collected on the female fibromyalgia participants with their verbal consent before participating in to the study. All participants were divided into two groups, group 1 (N=15) and group 2 (N=15). Both the groups received the same protocol of treatment that included neck exercises and static stretching of upper neck. The only difference between both the groups was that, group 1 received high frequency Transcutaneous electrical nerve stimulation (TENS) of more than 50 Hz for 20 minutes. The pain intensity was assessed on the VAS scale before and after completing the treatment procedure. In addition, other symptoms were also assessed, such as: depression, anxiety, fatigue, sleeps symptom, work performance and social life of the included participants with the revised Fibromyalgia Impact Questionnaire (FIQR). The same physical therapist made the initial and final assessment and led the treatment. Tender point on the upper trapezius muscle was selected for the TENS application and adjunctive therapy, since hyper analgesia in the muscle seen frequently in patients with fibromyalgia.

### Data Analysis

Data was entered and analyzed on SPSS version 20. All qualitative variables were presented as frequency and percentages, whereas quantitative variables were presented as mean and standard deviation. To check the significance of both the treatment, Paired t-test was applied with P value less than 0.05 considered as significant.

### Ethical Consideration

The data remained confidential and subjects were fully educated about the study objectives. A verbal consent was obtained from the participants after illuminating the study. Patient privacy and hygiene factor also maintained properly.

## RESULTS

Inter-group baseline comparison was conducted for the variable pain. The data was analyzed which included mean,  $\pm$  standard deviation, minimum and frequencies, maximum age, occupation and marital status. Groups (TENS and without TENS) were used as descriptive statistics to summarize the data.

The descriptive statistics of table I shows the minimum and maximum age mean  $\pm$  SD ( $40.37 \pm 10.74$ ) of both the groups (N=30) of the study. According to the marital status in the data, 76.7% were married women, 16.7% being single women whereas, 3.3% were widows and divorcees. Furthermore, according to the occupation 46.7% were

**Table 1: Demographic information**

Age	
mean+std	$40.37 \pm 10.74$
min, max	28, 65
Marital Status	
Married	23 (76.70)
Single	5 (16.70)
Widow	1 (3.30)
Divorce	1 (3.30)
Occupation	
House wife	14 (46.7)
No work	4 (13.3)
Teacher	3 (10.0)
Student	2 (6.7)
Other	7 (23.3)

housewives, 13.3% perform less work, 10% were teachers, 6.7% were students and 23.3% were belonging to other profession.

The expressive statistics (table II) shows a useful statistics for both groups 1 and 2. The tables show the pre VAS and post VAS of the treatment efficiency. The sample size is 30, group 1 (N=15) and group 2 (N=15), female age ranges from 20 to 65 years.

**Table 2: Paired samples Statistics of both the groups**

Groups	VAS scale	N	Mean $\pm$ SD
Tens	Before the treatment	15	$6.87 \pm 0.834$
	After the treatment	15	$0.87 \pm 0.834$
No Tens	Before the treatment	15	$7.00 \pm 0.655$
	After the treatment	15	$60.73 \pm 0.961$

Paired t-test applies with respect to groups. In group 1 (N=15), Tens with exercise therapy - before the treatment, the VAS scale  $6.87 \pm 0.834$  and after the treatment the VAS scale was  $0.87 \pm 0.84$  whereas, the group 2 (only exercise therapy) before the treatment  $7.00 \pm 0.655$  and after the treatment the VAS scale  $0.73 \pm 0.96$  was recorded respectively.

As table III shows the mean  $\pm$  SD of group 1 (N=15) is  $6.00 \pm 1.134$  and group 2 (N=15) was  $6.26 \pm 1.16$  by applying the paired sample test.

**Table 3: Comparison of the VAS of both the groups before and after the treatment**

Groups	Mean $\pm$ SD
TENS (before-after)	$6.000 \pm 1.134$
No TENS (before-after)	$6.267 \pm 1.163$

As the combination of both the groups, results, it shows significant consequences and there is no huge difference between both the treatment and the group 1 shows more significant results as compared to group 2 in the VAS scale and reducing the pain.

Ultimately, our results show improvement and in FIQR questionnaire also, we found healthier consequences in relation to depression, anxiety, fatigue, sleep symptoms, work performance and social life.

## DISCUSSION

This study included exercise regime as an intervention, that comprised aerobic and static stretching exercises at the level of upper cervical region (trapezius and supraspinatus), given to two groups. From these two groups, group 1 has received high frequency TENS therapy along with the exercise regime that is combined therapy, while group 2 received only exercises.

In Physiotherapy, TENS has a traditional use in reducing pain. The procedure by which pain modulation occurs with the use of TENS is still unknown. In 1965, Melzack and Wall proposed the mechanism of the analgesia that is produced after the application of TENS, in the gate control theory<sup>20</sup>. Exercises play very important role in relieving pain in several chronic muscular conditions. To improve the Activity of Daily Livings (ADLs) and wellbeing in women, the supervised exercise program is found to be very successful<sup>21</sup>. FM symptoms can be reduced by the effective use of exercises<sup>22</sup>. According to the study by Dadabhoy and Clauw, the most effective intervention to treat fibromyalgia is exercise and second to that is cognitive behavioral therapy<sup>23</sup>. A meta-analysis of six studies also revealed that aerobic-only exercise had high-quality effects on general well-being and comfort of patients. Moreover, great improvement in the signs and symptoms were observed. Bergman in its article illustrated that, emotional and cognitive factors determines how a patient responds to sensory input and perceives pain and thus modifies the behavior and attitude towards pain that can increase pain threshold in patients with fibromyalgia. Studies also show meditation, relaxation and stress management options as an efficient adjuvant

treatment<sup>24</sup>.

The results found in this study indicates that, the functional status and quality of life improved in group 2 since they were receiving effective exercise regime as compared to the group 1 who was receiving the combined therapy. This means that the effectiveness of exercises has a vital role in relieving FM pain.

According to the meta-analysis written by Kelley et al, they found that the Quality of Life and general wellbeing has improved a lot in women through exercises suffering with FM measured by FIQR<sup>25</sup>, while in another study done by Thomas et al, moderate evidence was found related to aerobic exercises and pain in FM, after the data analysis in their review<sup>26</sup>.

Whereas, from clinical perception, it is difficult to treat FM and patients present with comparatively severe levels of disability, but without obvious markers of pathology. Recently, a study by Walitt et al, conducted in 2011 consisted of longitudinal data from 1555 FM patients revealed that, over the course of 10 years, most patients experienced fluctuation in symptom severity, 35–40% of patients steadily worsened, and only 25% improved gradually over time<sup>27</sup>.

Some of the systemic reviews have a doubt on efficacy of exercises in fibromyalgia<sup>28</sup>, while others show little or no effect on pain or tender point, whereas other shows significant improvements. But in our study, we have found significant results in both the groups, group 1 show more significant results as compared to group 2 in the VAS scale and reducing the pain.

Carbonario et al, found in their study that, High frequency TENS in association with aerobic and stretching exercises is effective in treatment of FM symptoms, as compared to the TENS or exercises alone<sup>29</sup>. But in our study, there is no such huge difference found between the groups.

To assess the current health (physical function, symptoms) of patients with fibromyalgia in clinical and research settings the FIQR are frequently used and applicable for the better and authentic results. The FIQR was developed from information gathered from client reports, functional status instruments, and clinical observations. This instrument measures physical functioning, work status, depression, anxiety, morning tiredness, pain, stiffness, fatigue, and well-being over the weeks.

There was significant improvement found in depression, anxiety, fatigue, sleep symptoms, work performance and social life through FIQR. We build that, our protocol of invention with TENS yielded significant and was clinically important in several of these symptoms, and it may be moderately improved in the pain also. Furthermore, fibromyalgia is a multi-factorial disorder, our study suggested that, the combination of different physical therapy techniques, modified according to the therapist assessment and patients needs; it is an also effective option to treat the disorder.

## CONCLUSION

This study was conducted to find out the effectiveness of high frequency Transcutaneous electrical stimulation at the tender point of upper cervical as adjunctive therapy



of fibromyalgia patients, the results interpreted that after multiple treatment sessions, there is significant reduction in pain intensity as well as in other signs and symptoms. However, there was no huge significant difference found between both the groups, high frequency TENS and adjunctive therapy at the tender point of upper cervical in fibromyalgia.

## ACKNOWLEDGEMENTS

My respect and appreciation go to the teachers and my guiders who direct me in a use full path to perform good efforts and the space to accomplish this commonly has to be carved out of non-existent spare time. I truly cannot thank any of you enough. I wish to express gratitude to Pakistan Journal of Rehabilitation team; on the way to encourage me to entre in the world of evidence based practice. My profound thanks also go to the remarkable group of health care professionals who have contributed their time and efforts to collect the data of the research.

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