EFFICACY OF BURST TRANSCUTANEOUS ELECTRIC NERVE STIMULATION (TENS) IN PAIN MANAGEMENT AND THERAPY

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A thesis submitted in partial fulfillment of the requirements of the degree of MS Biomedical Engineering and Sciences

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Declaration

I, Shahram Yusuf Khan, certify that this research work titled “Efficacy of Burst Transcutaneous Electric Nerve Stimulation (TENS) in pain management and therapy” is my own work. The work has not been presented elsewhere for assessment. The material that has been used from other sources has been properly acknowledged / referred.

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Copyright Statement

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Author

Shahram Yusuf Khan

Dedication

This is dedicated to my forever interested, encouraging and always enthusiastic parents

Fareed Yusuf Khan & Dr. Rubina Fareed

Abstract

Burst Transcutaneous Electric Nerve Stimulation (TENS) is a form of pain therapy that offers strong contractions at lower frequency. It combines the efficacy of low-TENS and the comfort of conventional high-TENS. The waveform used in most common TENS device is Asymmetrical Biphasic Modified Square Wave pulse. Burst-TENS stimulates both nerve types simultaneously, thereby activating the AB sensory fibers and the pain gate mechanism and by the rate of burst, each burst will produce excitation of the AD fibers therefore stimulating the opioid mechanism. A randomized control trial (RCT) was conducted at the National Institute of Rehabilitative Medicine in Islamabad to form the Interventional Group and the Control Group of participants based on their advised treatment method. Visual Analogue Scale (VAS) was used as a pain scale index to record pre-treatment and post-treatment scores between 0 and 10. Screening and case reporting of each participant was followed by using statistical tools to record significant changes in pain intensities of both groups. Analysis of variation (ANOVA) was applied to analyze the difference among group means. Burst- TENS reduces pain intensity significantly better than routine therapy (heat and exercise). TENS physiotherapy is safe, inexpensive and patient friendly. It has no adverse or side-effect compared to pharmaceutical intervention.

Table of Contents

Thesis Acceptance Certificate iii

Declaration iv

Plagiarism Certificate v

Copyright Statement vi

Dedication viii

Abstract ix

List of Figures xii

1 Introduction 1

1.1 Electrotherapy in pain management 1

1.2 History 1

1.3 Transcutaneous Electric Nerve Stimulation (TENS) 2

1.3.1 Typical Features of TENS Waveform 2

1.4 TENS Devices 3

1.5 TENS Parameters 4

1.5.1 Current Intensity 4

1.5.2 The Pulse Rates 5

1.5.3 Width of the Pulse 5

1.6 Alternative Modes of TENS 5

1.6.1 Based on Frequency 5

1.6.1.1 High Frequency 6

1.6.1.2 Low Frequency 6

1.6.2 Based on Pattern 6

1.6.2.1 Burst 6

1.6.2.2 Continuous 7

1.6.2.3 Amplitude Modulated 7

1.7 Electrodes and Electrode Placement 7

1.8 Hazards and Contraindication of TENS 7

1.9 Precautions 8

1.9.1 Skin Irritation 8

1.9.2 No Pain Relief 9

1.9.3 Electrodes Dry Out 9

1.9.4 Skin's Resistance to TENS 9

1.10 Pain Scale Index 9

1.10.1.1 Schmidt Sting pain index 10

1.10.1.2 McGill pain index 11
1.10.1.3 Visual analogue scale (VAS) 12
1.11 Thesis Overview 12
1.11.1 Aims and Objectives 13
2 Literature Review 14
2.1 Context of Research 14
2.2 Significance of Research 14
3 Methodology 15
3.1 Product specification 15
3.2 Data acquisition 15
3.3 Participants 16
3.4 Screening of subjects 17
3.5 Participant Demographics 18
3.6 Randomized Control Trial (RCT) 19
3.6.1 Interventional Group 19
3.6.2 Control Group 19
3.7 Case Report Forms 20
4 Results 22
4.1 Tools of Acquiring Results 22
4.2 CRFs of Interventional and Control groups 22
4.3 Interaction Effect of Time and Group 23
4.4 Main Effect of Time (Pre- and Post) 24
4.5 Post-HOC Tukey Test 25
5 Discussions 26
5.1 Mechanism of action of TENS 26
5.1.1 The Pain Gate Mechanism 26
5.1.2 The Endogenous Opioid System 27
5.2 Efficacy of Burst TENS 28
5.3 Limitations 29
5.4 Conclusions 30
6 References 31

List of Figures

Figure 1.1-TENS pulse with amplitude and pulse duration 3
Figure 1.2-Schematic diagram of the output characteristics of a standard TENS device. 3
Figure 1.3-Variables on modern TENS Devices. 4
Figure 1.4-Quantification of pain picture. 10
Figure 1.5-Schmidt Pain Index 10
Figure 1.6-McGill Pain Index 11
Figure 1.7-VAS Pain Scale Chart 12
Figure 3.1-Patient Consent Form 16
Figure 3.2-Inclusion Criteria 17
Figure 3.3-Exclusion Criteria 17
Figure 3.4-Demographic block diagram. 18
Figure 3.5-Randomized Control Trial (RCT) 19
Figure 3.6-Case Report Form 20
Figure 4.1-Pain intensity scores of subjects of both groups. 22
Figure 4.2- One way ANOVA 23
Figure 4.3-Interaction effect of time and group. 23
Figure 4.4-Mean effect of time. 24
Figure 4.5-Post HOC Tukey test. 25
Figure 5.1-Pain gate mechanism 27
Figure 5.2-Endogenous opioid mechanism 28
Figure 5.3-Burst- Transcutaneous Electric Nerve Stimulation 29

1 Introduction

1.1 Electrotherapy in pain management

To alleviate muscle and joint pain Electrotherapy, commonly practiced in the field of physical therapy, used to be prescribed (Vance, Dailey, Rakel, & Sluka, 2014). The following ailments are treated with the help of electrotherapy according to the American Physical Therapy Association:

- Management of pain
- Treatment of neuromuscular dysfunction
- Range of joint mobility is improved
- Repair of tissue
- Acute and chronic edema can be treated
- Peripheral blood flow improves
- Urine and fecal incontinence gets better
- Lymphatic Drainage is also improved

Muscle spasms are relaxed with the help of electrotherapy which is considered its main use. Other than that, the circulation of blood increases, rehabilitates muscle stimulation, plays a role in improving motion of the muscle, manages constant and unmanageable cramps along with piercing pain felt after trauma and acute pain experienced after surgeries. An addition to its many uses, electrotherapy promotes stimulation of muscles right after surgeries to prevent venous thrombosis and aids in mending wounds (Jones, Anaesthesia, &, & 2009.).

1.2 History

Ancient Egyptians (2,500B.C.) soothed painful body parts with the application of electrogenic fish which is proof that using electricity to relieve pain is a technique used since time immemorial. However, 1960s saw the establishment of pain in medical books and it was not until the 1970s when the field of medicine fully recognized and dedicated a research journal (*Pain*) and association (International Association for the Study of Pain).

Reason for the popularity of electrotherapy were the electrostatic generators in the 18th century but pharmacological treatments were more popular which led to the decline in the use

of electrotherapy towards the end of the 19th century. In 1965, using electricity to alleviate pain was seen in a new light with "Pain Mechanisms: A New Theory," published by of Melzack and Wall's which bore studies to the effect that inhibiting central transmission of noxious information could be done by using electrical stimuli. Clinical observations confirmed that pain could considerably be reduced in patients with the help of electrical stimulation of peripheral afferents, dorsal columns and descending pain inhibitory pathways. (Scholten, Stanos, Rivers, …, & 2018.).

The origin of pain, a complex clinical problem, is almost always unclear. Verbal reports and observations are depended upon for assessment while cognitive and affective factors may modify a patient's physical perceptions (Turk & Gatchel, 2018). New therapeutic alternatives have developed from theoretical perspectives and research, and the projection of pain as a problem has grown since 1945. Dorsal column stimulation implants through Transcutaneous Electric Nerve Stimulation (TENS) was initially used until it was discovered that TENS could be used on its own (pain & 2007.).

1.3 Transcutaneous Electric Nerve Stimulation (TENS)

In cases with long term ceaseless pain or unmanageable pain, the most modern way to manage it via TENS due to its noninvasive and non-pharmacological intervention. By using TENS underlying nerves are activated by delivering electricity to intact surfaces of the skin. (J. DeSantana, Walsh, Vance, & 2008.). Side effects or drug interactions of TENS and titrate dosage when self-administered by the patient must be kept in mind during treatment.

Most muscle related pain and sports injuries e.g. carpel tunnel syndrome, RSI (repetitive strain injuries) as well as injuries related to other working conditions can be relieved with TENS.

1.3.1 Typical Features of TENS Waveform

The absence of net DC component (described by manufacturers as 'zero net DC') is the reason why TENS waves are asymmetrical bi-phasic modified square wave pulses. This ensures the least skin reactions because of the buildup of electrolytes under electrodes (Johnson, 2014).

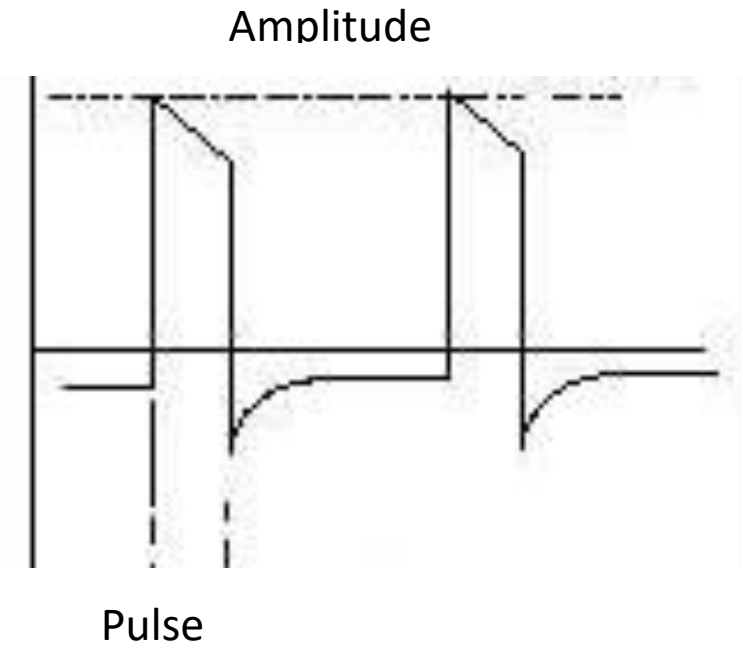

Figure 1.1-TENS pulse with amplitude and pulse duration

1.4 TENS Devices

TENS apply alternating current with the help of cutaneous electrodes that are placed near the painful area by small, battery powered devices in which pule frequency and intensity are adjustable because they are connected to TENS efficacy.

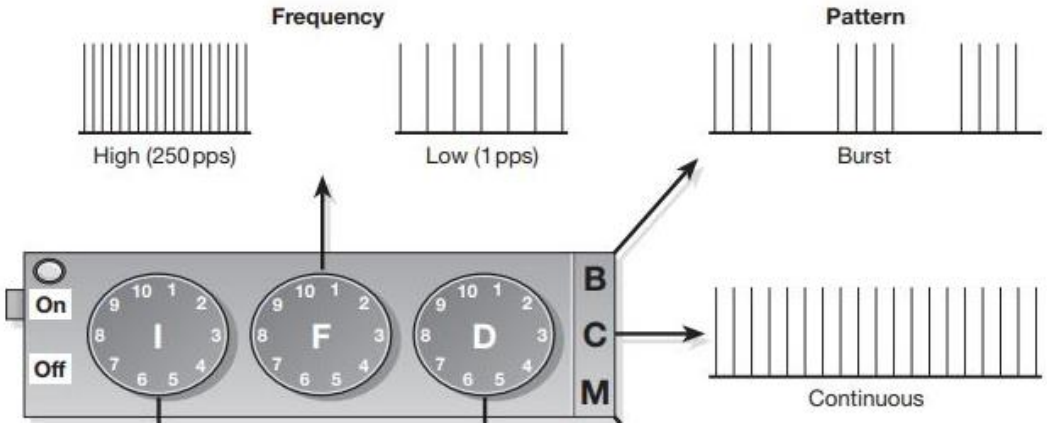

Figure 1.2-Schematic diagram of the output characteristics of a standard TENS device.

In figure 2, the lines represent a single pulse. The current amplitude of the pulses is administered by the intensity control dial (I) while the pulses per second are administered by the frequency control dial (F). The time duration of each pulse is determined by the pulse duration control dial (D). Burst, continuous and amplitude modulation are the different arrangements of pulse delivery offered by most TENS devices (Johnson, 2007).

1.5 TENS Parameters

Current intensity, pule rate/frequency and duration of pulse and burst mode(in which pulses go out at a rate of 2-3 bursts per second) are all part of TENS (Liebano, Rakel, Vance, PAIN®, & 2011.).

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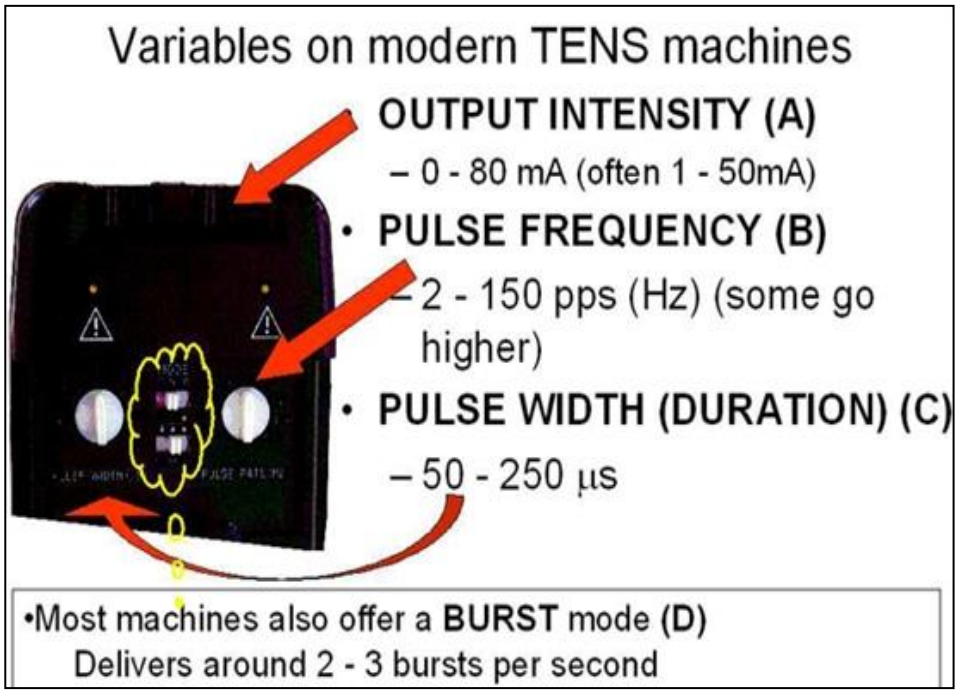

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Figure 1.3-Variables on modern TENS Devices.

1.5.1 Current Intensity

The degree of current or voltage utilized by the TENS unit is referred to as the intensity which is normally in the form of an even current or constant voltage output, the strength of which is calculated in volts and that of a consistent current unit is calculated in milliamps. Some machines provide outputs up to 100mA, but the typical range of current intensity is usually 0-80mA. Since the primary target of the therapy is the sensory nerve, even a small

amount of current is enough as long as the current passes through the tissue to depolarize these nerves ("Transcutaneous Electrical Nerve Stimulation (T.E.N.S.) unit for pain management and replacement electrodes.," n.d.).

1.5.2 The Pulse Rates

The pulse rate or frequency (B) of electrical energy which the machine delivers usually varies from about 1 or 2 pulses per second (pps) up to 200 or 250 pps measured in Hertz or Hz (Chen, Tabasam, Physiotherapy, & 2008, n.d.). In order to be effective clinically, TENS machine needs to work with 2-150 pps (or Hz).

1.5.3 Width of the Pulse

Around 40-250 micro seconds (ms) could be the duration of each pulse (C) but recent proof shows that this is not as important a control as the fervency or frequency and the most important being proper setting in the clinic which is estimated to be around 200ms(Vance et al., 2014).

The sensory nerves have a relatively low threshold and since they are the target, short duration of pulses is used. Sensory nerves respond rapidly to change of electrical state so excitation below a millisecond is enough to depolarize it.

1.6 Alternative Modes of TENS

A TENS user can usually choose between continuous, burst and modulated outputs of which the first two kinds are self-explanatory. For the convenience of the patient and to overcome accommodation of nerve fibers, the patient can use modulated output (Amjad, Shahid, Batool, Ahmad, & Ahmed, 2016).

1.6.1 Based on Frequency

The patient can use different frequencies (number of pulses per second) based on their need. For instance a frequency of 2000Hz means 200 pulses delivered per second(Turk & Gatchel, 2018).

1.6.1.1 High Frequency

The most commonly used is Conventional or High frequency/Low intensity TENS with high frequency (above 100 Hz) and short pulse duration (50-80µs) which stimulates the Group II (Aß) afferent nerve fibers (Amjad et al., 2016). No muscle contraction and a sensation of comfortable paranesthesia (pins and needles) is produced by Conventional TENS even though some contraction is seen with higher intensities when electrodes are placed over a motor point. TENS mode achieves analgesia by spinal segmental mechanism, i.e. pain gate theory (due to local neurophysiological mechanisms) when Group II fibers are accelerated. Even though analgesia happens rapidly, it only lasts for a few hours after treatment.

1.6.1.2 Low Frequency

The analgia lasts longer than Conventional TENS when Acupuncture-like or low frequency/high intensity (enough for muscle contractions that can be seen) and a lengthy duration of pulse (~200µs). This type of TENS stimulates the Group III (Aδ) and IV (C) nociceptive fibers and small motor fibers. The electrodes should be placed in such a manner that the muscle contractions can be seen clearly (e.g. muscle on painful area) since TENS needs afferent signals from muscle receptors. Paranesthesia and muscle twitching(contraction) is experienced by this method(Fuentes, Armijo Olivo, Magee, & Gross, 2010). Endogenous opioids are released through the descending pain suppression system in this method which leads to typically longer duration of analgia.

1.6.2 Based on Pattern

Pulse patterns can be continuous, modulated or burst based on the patient's need and the desired result. Each uses different frequency modes of TENS (Cheville, Smith, North, & 2018, n.d.).

1.6.2.1 Burst

Conventional and Acupuncture-like TENS together form Burst mode of TENS which uses baseline low frequency (1-4 Hz) current in combination with high frequency (100 Hz) trains or pulses. This produces a tolerable muscle contraction which some patients prefer. It stimulates both nerve types simultaneously to activate the pain gate mechanism and opioid

mechanism which is a result of the combination of efficacy of low-TENS and comfort of high- TENS.

1.6.2.2 Continuous

This mode of TENS is often used for agonizing procedures such as getting rid of sutures because it uses a great frequency (100-150 Hz) and lengthy time of pulse (150- 250µs) on patients at the highest bearable intensity for less than 15 minutes.

1.6.2.3 Amplitude Modulated

When there is a change in either pulse duration, frequency or amplitude parameters in a cyclic way, it is called a modulated output and sometimes two or all three of these parameters are modulated so cyclic modulation in amplitude takes place which increase from zero to a level set beforehand then back to zero again.

1.7 Electrodes and Electrode Placement

Carbon electrodes can be applied with wet gel or hydrogel while the self-adhesive ones are easier to use in TENS for many pain conditions and can be found in a number of shapes and sizes. One must keep allergic reactions. Cost, ease of use and availability in mind while choosing which type of electrode to use. In addition, the therapist must try several sites for treatment which involves a degree of 'trial and error' as ineffective positioning of electrode is one of the main reasons for luke-warm reaction to TENS treatment. TENS electrodes can be used on painful areas, peripheral nerves, spinal nerve roots and other specific points (acupuncture, trigger and motor points), the stimulation of which will most likely result in passing clear information into the central nervous system ("Transcutaneous Electrical Nerve Stimulation (T.E.N.S.) unit for pain management and replacement electrodes.," n.d.).

However, reason and point of the pain must be determined for accurate assessment.

1.8 Hazards and Contraindication of TENS

Before the first application, contraindications such as the following must be ruled out for potential TENS users (Vance et al., 2014).

- TENS is carried out on areas of the skin with whole sensation and if there is a lack of it, then it is dangerous to carry out the process as the skin can burn due to the intensity of the treatment. A simple sharp/blunt test is sufficient to check whether the skin is healthy enough. Needless to say, that treatment does not work if the appropriate afferent nerves are not stimulated.
- Patients should not undergo treatment if they are incapable of comprehending the therapist's directions clearly. They should preferably be in complete control of their senses if they are required to operate a TENS unit on their own.
- Placing the electrode on a carotid sinus in the neck which are placed at the base of the internal carotid arteries can make blood pressure drop. Baroreceptors are used to keep an eye on the change in blood pressure.
- Pregnancy is considered a contraindication to TENS. The electrodes should not be placed over the pregnant uterus and some sources reject the use of TENS for any painful area during pregnancy even though no adverse reactions have been noted yet (Amjad et al., 2016).
- Certain cardiac pacemakers and defibrillators do not work well with TENS and have been shown to interfere with its working. A patient's cardiologist must be consulted by the clinician before going ahead with TENS therapy for such patients. ECG/Holter monitoring should be done when a patient with a pacemaker is considered for TENS treatment.
- Clinician must change the electrode if there is an allergic reaction to the electrode, gel or tape which can immediately be figured out in the first treatment.
- Epileptic patients can only be treated if the clinician deems it fit.
- While using machinery or driving, patients should not be exposed to TENS.

1.9 Precautions

The high intensity required for visible muscle contractions needed for TENS is intolerable for some individuals (Prentice, 2017).

1.9.1 Skin Irritation

It is mandatory to figure out the cause of a skin irritation as to whether it is a reaction to electrode/tape/gel or wearing TENS and then allow the skin to heal before further treatment/ The electrode can be applied to the peripheral nerve or spinal nerve roots while the skin is

healing. Another type of electrode should be tried out if the user is allergic to the type being used. The electrode must be removed, and the skin must be allowed to breathe for at least an hour after TENS treatment.

1.9.2 No Pain Relief

Different electrode placement sites must be tried and the whole process must be followed meticulously, as many people are unresponsive to TENS. The results of Conventional and Acupuncture-like TENS must be compared as part of the process (Fuentes et al., 2010). If all the options have been tried such as placing the electrode in different areas and there is still no relief from pain, then it is understood that the user is not responding to TENS

1.9.3 Electrodes Dry Out

A few drops of water can be used to improve the adhesiveness of self-adhesive electrodes, and then they can be let to air dry. However, the instructions of the manufacturer need to be followed to do so.

1.9.4 Skin's Resistance to TENS

The intensity needs to be kept very high for patients using skin moisturizers and creams as they make the skin resistant to electrical current. The skin is cleaned with soap and water or an alcohol swab as preparing the skin to apply electrodes is an important part of the process.

1.10 Pain Scale Index

Pain is subjective and directly proportional to numerous factors of nature and nurture which is why its quantification is a challenge. Having a clear idea of the intensity, kind, and length of discomfort, makes it possible to achieve a definite diagnosis, come up with a treatment plan, and assess whether the treatment is adequate.

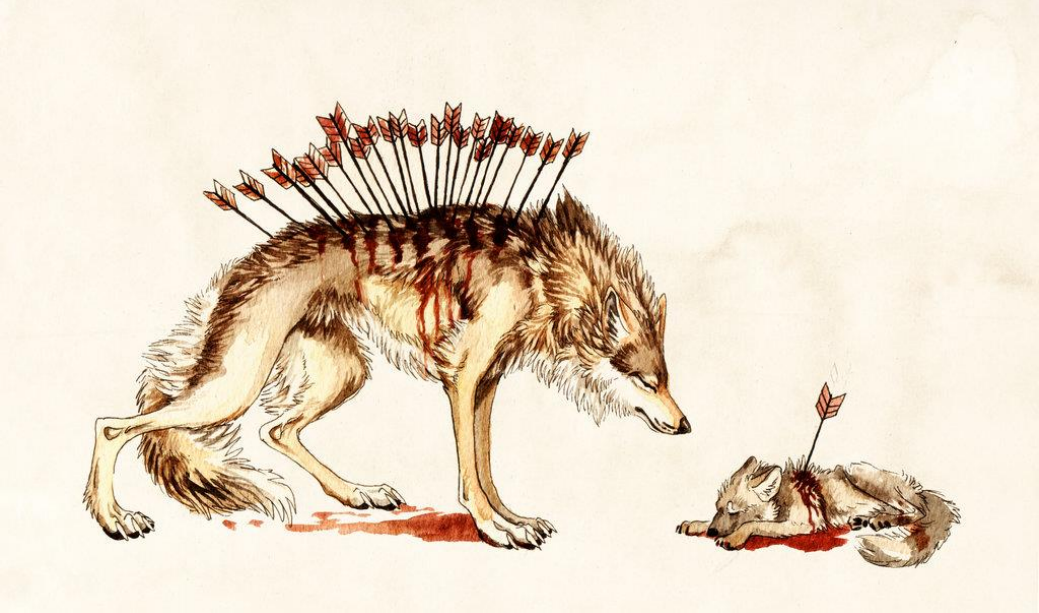


Figure 1.4-Quantification of pain picture.

1.10.1.1 Schmidt Sting pain index

During the literature review the Schmidt sting pain index was studied. This was developed to assess relative pain caused by different hymenopteran stings. It is mainly the work of Justin

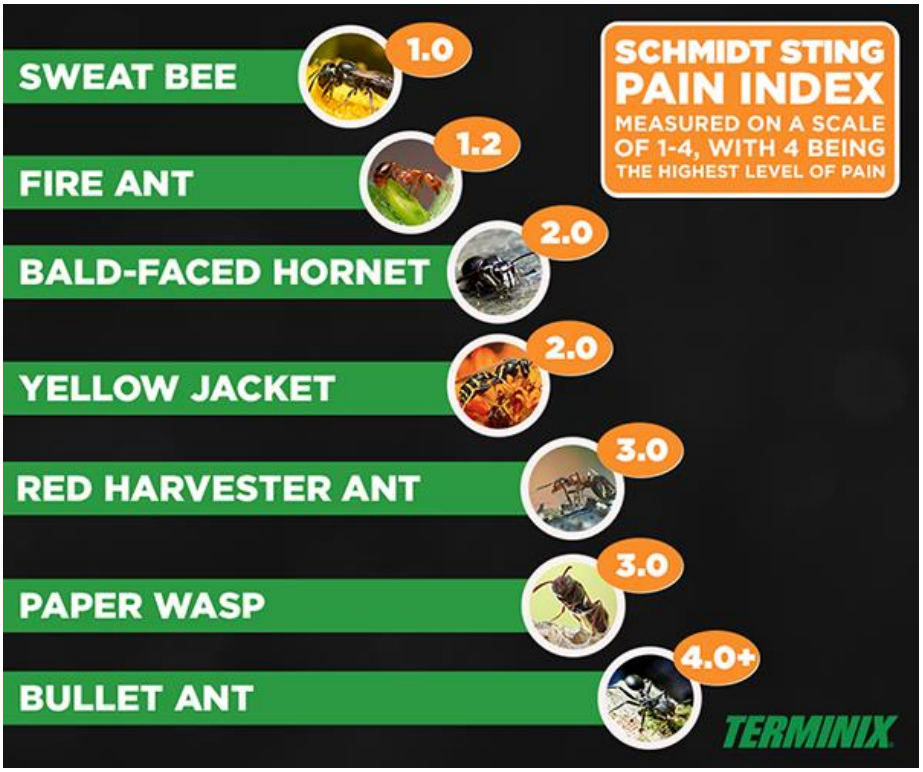


Figure 1.5-Schmidt Pain Index (https://www.terminix.com/blog/science-nature/the-insect-sting-pain-scale/)

O. Schmidt (born 1947), who was an entomologist at the Carl Hayden Bee Research Centre in Arizona.

Schmidt claims to have been stung by the majority of stinging Hymenoptera. It ranges from a scale of 1 to 4 (Sweat Bee to Bullet Ant respectively).

1.10.1.2 McGill pain index

Another pain index studied was the McGill Pain Questionnaire, which was developed at McGill University in 1971. This type is a self-report questionnaire that involves words used to describe

pain, a list of 78 words are categorised into 20 groups. The user marks the words that best describe their pain (multiple markings are allowed).

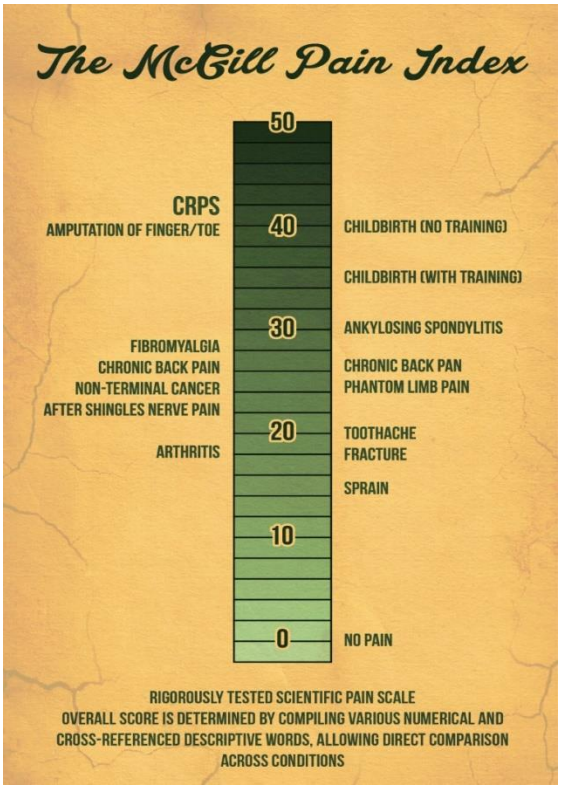


Figure 1.6-McGill Pain Index (http://princessinthetower.org/how-to-manage-and-treat-complex-regional-pain-syndrome)

1.10.1.3 Visual analogue scale (VAS)

Visual Analogue Scale (VAS) was used in this study to generate pain intensity scores. Subjects were thoroughly explained this assessment tool.

The Schmidt sting pain index was rejected due to the unavailability of relevant insects and difficult for local population to relate to the mentioned hymenopteran stings.

The McGill pain index was not used as it is based on 78 words describing pain which would have been difficult to contextually translate into national/regional language.

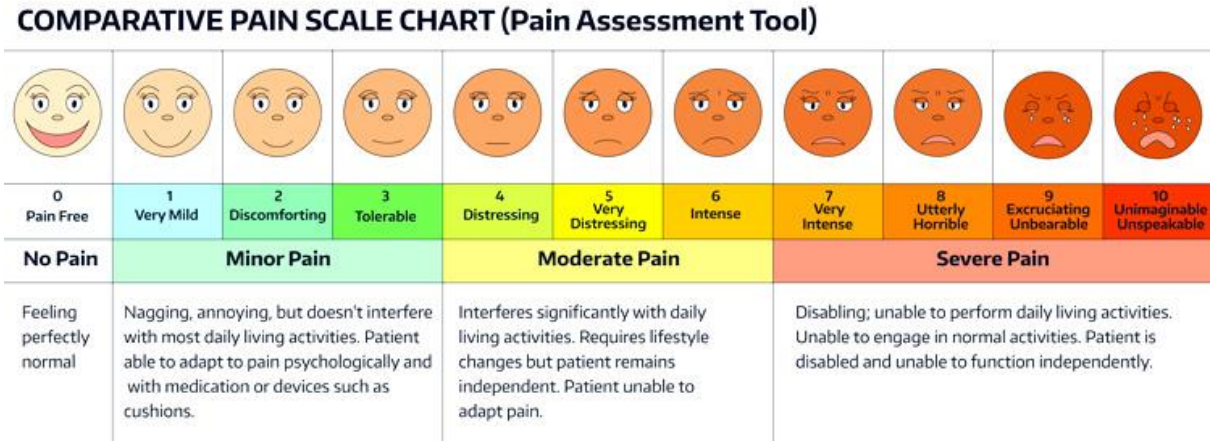


Figure 1.7-VAS Pain Scale Chart

For this study the VAS was determined to be the most relevant pain index after taking the above limitations into consideration.

1.11 Thesis Overview

This thesis is performed at the National Institute of Rehabilitative Medicine in G-8 Islamabad, Pakistan. This research glances into the fundamental complaint of patients i.e. pain management and therapy. A Randomized Control Trial (RCT) has been performed with each subject's consent in this study to better understand the efficacy of Transcutaneous Electric Nerve Stimulation (TENS) in pain management and therapy.

1.11.1 Aims and Objectives

- To investigate the role of Transcutaneous Electric Nerve Stimulation (TENS) in pain management and therapy.
- To generate correlational scores in pain intensities in the interventional group.
- To compare the efficacy of Burst –TENS with routine therapy.
- To find out direct influence of Burst TENS in physiotherapy based on patient vitals.

2 Literature Review

2.1 Context of Research

The context of this research revolves around the four most recent published articles on TENS and pain management. Several other published articles, journals and magazines were carefully studied during the literature review of this thesis.

- Comparison of the efficiency of TENS and therapeutic Ultrasound in the treatment of myofascial trigger points (2016). In this case the methodology used the Numerical Pain Rating Scale (NPRS) for evaluation of pain intensity and goniometer to check cervical range of motion.
- Use of Analgesic current therapies for improving pain and disability in management of neck pain (2017). This study used the Visual Analogue Scale (VAS) to assess pain intensity.
- A randomized to determine durations of application of acupuncture like TENS on patients with CLBP (2017). Sample of 11 participants with pain intensity assessed with the VAS before, during and after.
- Assessment of pain and importance of exercise in hip osteoarthritis (2017). Involved 20 patients and used the VAS scale. After a month there was a statistically significant reduction in pain measured by VAS (at the beginning it was 6,7; at the end 3,2).

2.2 Significance of Research

This type of research glances into the fundamental complaint of numerous patients. Patients with medical conditions complain of severe pain which they want to deal with on a priority basis. In therapeutic medicine, management of pain is right at the top and any decrease in such pain will be highly appreciated by the patient. This can bring rise to effective physiotherapy of patients with acute pain conditions.

3 Methodology

3.1 Product specification

TENS device used in this study had the following specifications;

- Dual-Channel Tens Stimulator, 2 Lead Wires, 4 Self Adhesive Electrodes
- Timer: 30 minutes, 60 minute or continuous mode selectable.
- Moulded Plastic Carrying Case, 9 Volt Battery, Operating Manual
- Power Indicator Light
- Wave Form: Asymmetrical biphasic square pulse.
- Pulse Amplitude: 0 to 80 mA each channel, adjustable, (500-ohm load)
- Pulse Rate: 2 to 120 Hz, adjustable
- Pulse Width: 40 to 260 microseconds, adjustable
- Mode Selector: Switch: Burst, Normal, Modulation
- B: Cycle Bursts, 2 Bursts/sec, 9 pulses/Burst, 100Hz width is adjustable.
- Maximum Voltage: 110 volts, open circuit
- Maximum Charge: 21 micro coulombs per pulse
- Power Source: 9-volt battery or similar rechargeable cell

3.2 Data acquisition

National Institute of Rehabilitation Medicine (NIRM) is a reputable institute established with an objective to enable healthcare delivery system to provide services according to the needs of the patients.

This research was conducted in the Physiotherapy department at NIRM in collaboration with Dr. Muhammad Ashfaq.

Numerous visits to the hospital and active interaction with patients ensured quality results. Pain intensity scores were recorded at the end of each session of eligible participants.

3.3 Participants

Subjects that were already undergoing therapy of all sorts at NIRM were picked for this study. Each participant was required to sign-off the patient consent form.

Patient Consent Form

مریض رضامندی فارم

Thank you for taking part in our research on pain management and therapy.

درد کے انتظام اور تھراپی پر ہماری تحقیق میں حصہ لینے کے لئے آپ کا شکریہ

The following physiotherapy has no harmful effects.

مندرجہ ذیل فزیوتھراپی میں کوئی نقصان دہ اثرات نہیں ہیں

Signature _____

Patient ID:

Signature _____

Shahram Y Khan
(Principal Investigator)

Figure 3.1-Patient Consent Form

Bi-lingual form was used to cater to patients from various socio-economic backgrounds. This form was duly signed after understanding by the participant, who was assigned a patient id, and the principal investigator.

3.4 Screening of subjects

An Inclusion/Exclusion Screening form to assess eligibility of all subjects was drafted.

Inclusion/Exclusion Screening Form

Efficacy of Transcutaneous Electric Nerve Stimulation (TENS) in pain management and therapy	
Site: National Institute of Rehabilitation Medicine (NIRM) G-8/2 Islamabad. **Patient_ID:** _____	**Visit Date:** __ __/__ __ __/ 2 0 _1_ _8_ d d m m m y y y y **Principal Investigator** Shahram Yusuf Khan
Group Type (circle one):	**INTERVENTIONAL** **EXPERIMENTAL**

Inclusion Criteria

Participant must:

1.	Inclusion 1: Be aged between 18 and 60	☐Yes ☐No
2.	Inclusion 2: Be able to give informed consent	☐Yes ☐No
3.	Inclusion 3: Be able to understand and communicate in English and/or Urdu	☐Yes ☐No
4.	Inclusion 4: Have experienced acute pain for at least 1 month.	☐Yes ☐No
5.	Inclusion 5: Have undergone routine therapy at NIRM prior to this	☐Yes ☐No
6.	Inclusion 6: Be able to share feedback on pain intensity pre- and post-treatment.	☐Yes ☐No

Note: All Inclusion Criteria must be answered YES, to be included in study.

Figure 3.2-Inclusion Criteria

Exclusion Criteria

Participant must not:

1.	Exclusion 1: Be suspected or diagnosed with any type of fracture	☐Yes ☐No
2.	Exclusion 2: Have a cancer or a history of cancer	☐Yes ☐No
3.	Exclusion 3: Suffer from any major ailment such as TB, Hepatitis etc.	☐Yes ☐No
4.	Exclusion 4: Wear an implantable device such as pacemaker, defibrillator or stent etc.	☐Yes ☐No
5.	Exclusion 5: Decline to comply with an exercise program during RT	☐Yes ☐No
6.	Exclusion 6: Experience pain potentially of labor or inflammatory origin	☐Yes ☐No

Note: All Exclusion Criteria must be answered NO, to be included in study.

Did the participant meet the eligibility requirements for this study? ☐ Yes ☐ No

Figure 3.3-Exclusion Criteria

The Screening form was filled out in consultation with each subject to ensure authenticity and recruitment of fit subjects. After the fulfillment each participant was assigned a group of either Interventional or Control based on their advised treatment.

3.5 Participant Demographics

Three subjects were excluded, two diagnosed with a fracture and another had pain of inflammatory origin.

This study was carried out with the approval of the School of Mechanical and Manufacturing Engineering Ethics Committee.

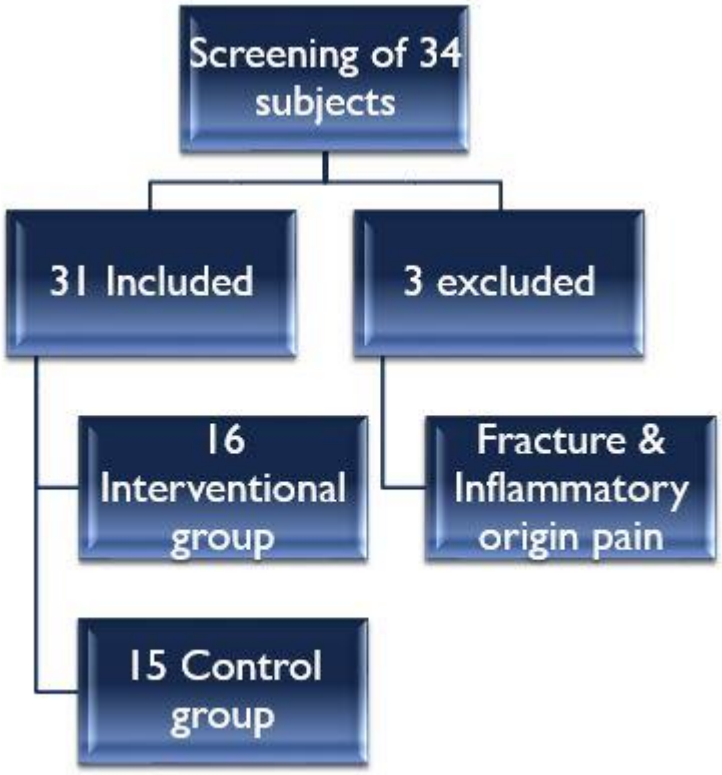


Figure 3.4-Demographic block diagram.

- The range of age of subjects was 21 to 71 years.
- Interventional group has 7 males and 9 females.
- Control group has 5 males and 10 females.

3.6 Randomized Control Trial (RCT)

RCT is a scientific experiment which lowers the chances of bias when trying out a new treatment.

The people participating in the trial are randomly allocated to either the group being treated under scrutiny or to a group getting standard treatment.

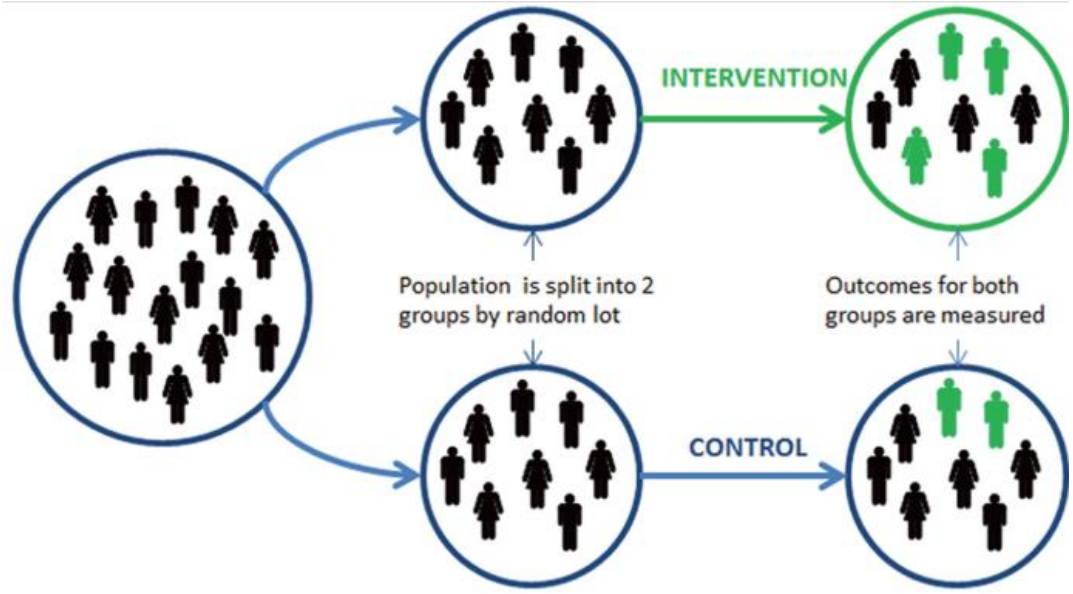


Figure 3.5-Randomized Control Trial (RCT)

The subjects in my study were assigned to different groups on the basis of their consultation with Dr. M. Ashfaq.

3.6.1 Interventional Group

Subjects in the Interventional group underwent one session of Burst-TENS treatment for 25 minutes.

Consequent outcomes were recorded.

3.6.2 Control Group

Subjects in the Control group underwent routine therapy (RT) which included heat and exercise.

Score outcomes were recorded on the CRFs.

3.7 Case Report Forms

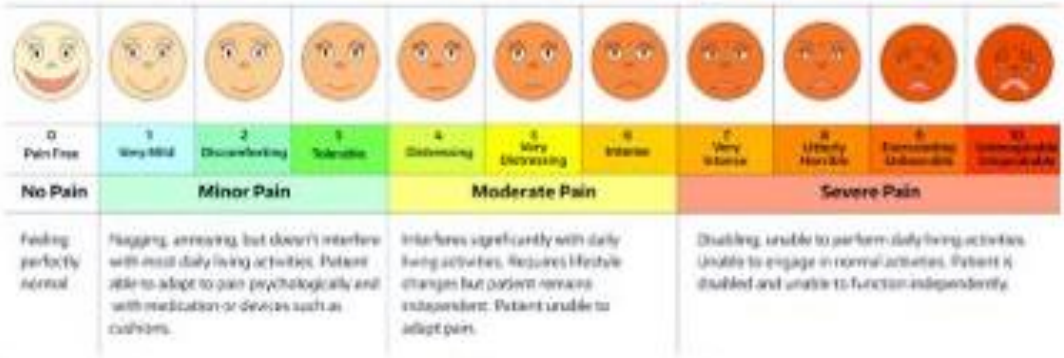
Case Report Forms (CRFs) were duly filled along with basic patient vitals including age, gender, height, weight, province of birth and diabetic history.

CASE REPORT FORM

PATIENT VITALS

- SEX _____
- AGE _____
- HEIGHT _____
- WEIGHT _____
- DIABETES (Y/N) _____
- PROVINCE OF BIRTH _____

COMPARATIVE PAIN SCALE CHART (Pain Assessment Tool)



PT_ID	PRE-TREATMENT	DURING	POST-TREATMENT

_____ GROUP

PRINCIPAL INVESTIGATOR: SHAHRAM YUSUF KHAN (SMME, NUST ISLAMABAD)

Figure 3.6-Case Report Form

The VAS was used to collect pain scores between 0 and 10 at;

- Pre-treatment
- During
- Post-treatment.

Pain was divided into three levels; minor, moderate and severe.

Each score level was well explained to subjects, sometimes using Urdu translations and examples.

Each CRF also had the allocated Patient ID for later identification purposes. At the bottom of the form the allocated group was also filled.

4 Results

4.1 Tools of Acquiring Results

Result scores were recorded for each group in an MS excel to use for statistical analysis.

Data was imported from MS Excel to apply statistical tools.

Statistica software was used to apply Analysis of variation (ANOVA) to analyse the differences among group means.

4.2 CRFs of Interventional and Control groups

Pain intensity scores between 0 and 10 were recorded during investigation and were tabulated as such;

Interventional Group						Control Group				
S.No	Pt_Id	Pre	During	Post		S.No	Pt_Id	Pre	During	Post
1	3	8	6	1		1	1	5	6	3
2	4	8	7	5		2	2	6	6	4
3	6	8	6	4		3	5	5	4	2
4	7	8	6	2		4	9	2	2	1
5	8	6	5	2		5	10	8	6	7
6	11	9	7	5		6	16	6	5	3
7	12	8	7	6		7	19	6	5	4
8	13	6	4	3		8	20	3	2	2
9	14	6	5	3		9	23	6	4	3
10	15	4	3	1		10	24	7	5	4
11	17	3	2	1		11	25	8	6	6
12	18	6	5	3		12	27	3	1	2
13	21	7	5	5		13	28	2	2	2
14	22	3	2	1		14	29	7	5	5
15	26	3	1	1		15	30	9	7	6
16	31	2	1	0		16				

Figure 4.1-Pain intensity scores of subjects of both groups.

4.3 Interaction Effect of Time and Group

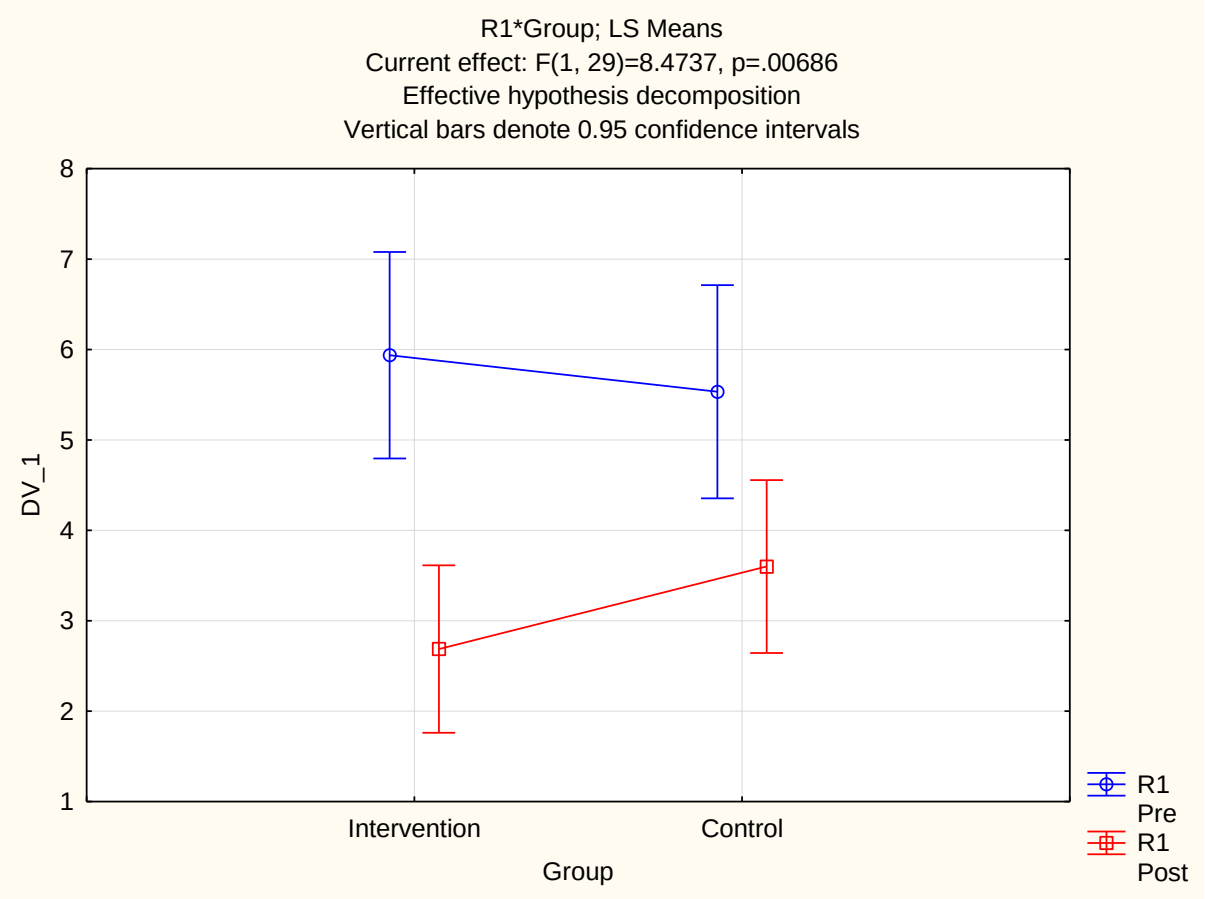


Figure 4.2- One-way ANOVA

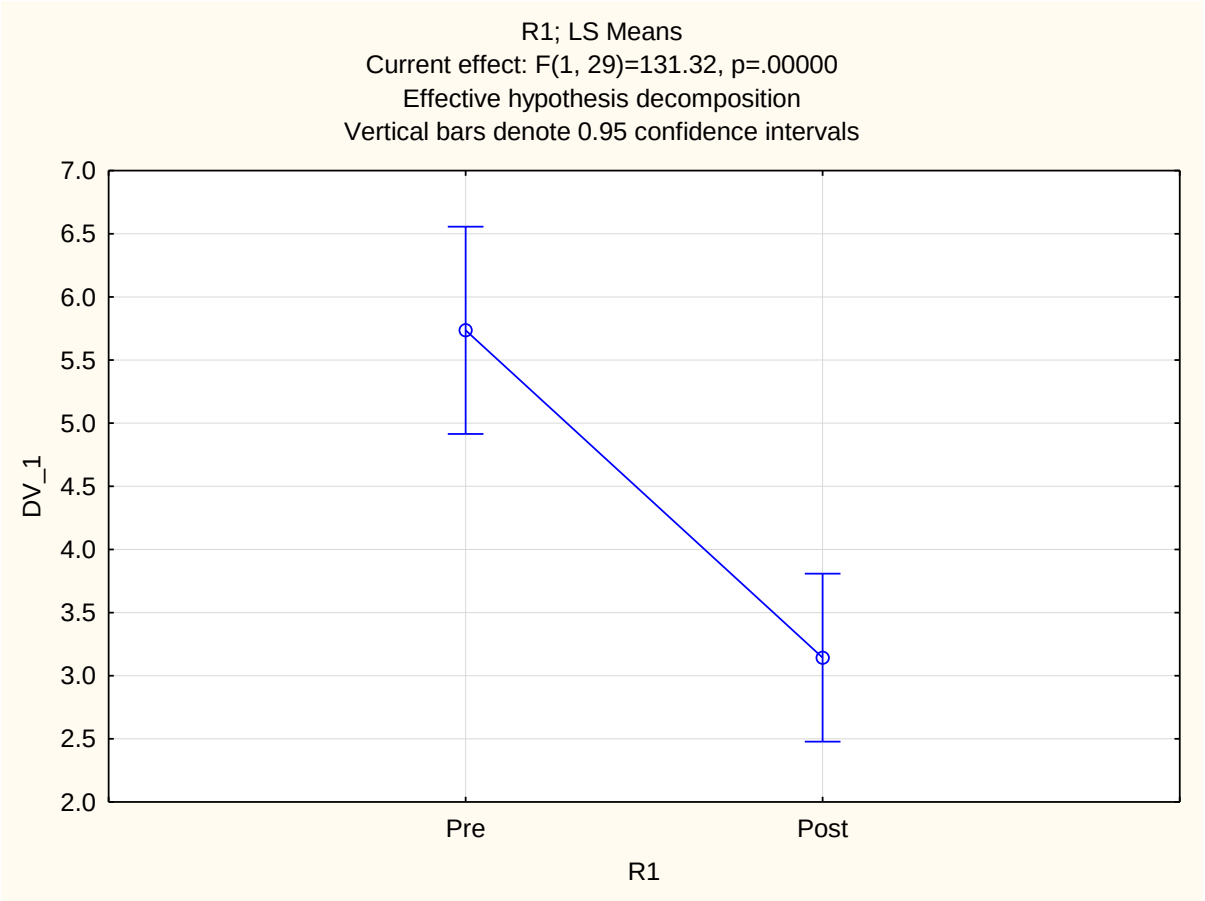
The average mean of the interventional group was at 5.93 before therapy and significantly dropped to 2.68 after therapy session.

R1*Group; LS Means (data.sta)
Current effect: F(1, 29)=8.4737, p=.00686
Effective hypothesis decomposition

Cell No.	Group	R1	DV_1 Mean	DV_1 Std.Err.	DV_1 -95.00%	DV_1 +95.00%	N
1	Intervention	Pre	5.937500	0.558382	4.795480	7.079520	16
2	Intervention	Post	2.687500	0.452573	1.761885	3.613115	16
3	Control	Pre	5.533333	0.576695	4.353861	6.712806	15
4	Control	Post	3.600000	0.467415	2.644028	4.555972	15

Figure 4.3-Interaction effect of time and group.

4.4 Main Effect of Time (Pre- and Post)



Cell No.	R1; LS Means (data.sta) Current effect: F(1, 29)=131.32, p=.00000 Effective hypothesis decomposition R1	DV_1 Mean	DV_1 Std.Err.	DV_1 -95.00%	DV_1 +95.00%	N
1	Pre	5.735417	0.401362	4.914538	6.556295	31
2	Post	3.143750	0.325307	2.478422	3.809078	31

Figure 4.4-Mean effect of time.

4.5 Post-HOC Tukey Test

Post-hoc Tukey test was applied for multiple group comparison.

Cell No.	NewVar	R1	{1} 5.9375	{2} 2.6875	{3} 5.5333	{4} 3.6000
Tukey HSD test; variable DV_1 (Spreadsheet8) Approximate Probabilities for Post Hoc Tests Error: Between; Within; Pooled MS = 4.1329, df = 35.078						
1	Intervention	Pre		0.000162	0.945142	0.014881
2	Intervention	Post	0.000162		0.002389	0.600770
3	Control	Pre	0.945142	0.002389		0.000168
4	Control	Post	0.014881	0.600770	0.000168	

Figure 4.5-Post HOC Tukey test.

5 Discussions

5.1 Mechanism of action of TENS

Firing up the sensory nerves and in turn activating natural pain-relieving systems such as The Pain Gate Mechanism and The Endogenous Opioid System is what a TENS unit does. Which mechanism to use depends on variation in stimulation parameter.

The choice of which mechanism to use for pain relief depends on the variation in stimulation parameter.

5.1.1 The Pain Gate Mechanism

The hind horns of the spinal cord has a gating system in which C fibers address pain and Aβ fibers carry sensation of pressure and light. In this theory, the two meet and the excitation of A beta (Aβ) sensory fibers happens. This lessens the carriage of stimulus from C fibers through the passage of the spinal cord and on to the higher centers (Hazime, Baptista, Pain, & 2017, n.d.)

Aβ fibers are most efficient when excited at a high rate (80 - 130 Hz or pps) (Bjordal, Johnson, & Ljunggreen, 2003).

Clinically, it is important to let the patient find the frequency that works best for their treatment, needless to say that it varies from person to person. Setting the machine beforehand at a certain frequency and then convincing the patient that it's what they need, does not relieve the patient of pain and is therefore least effective even though discomfort may be relieved to some extent (Maeda, Lisi, Vance, research, & 2007.).

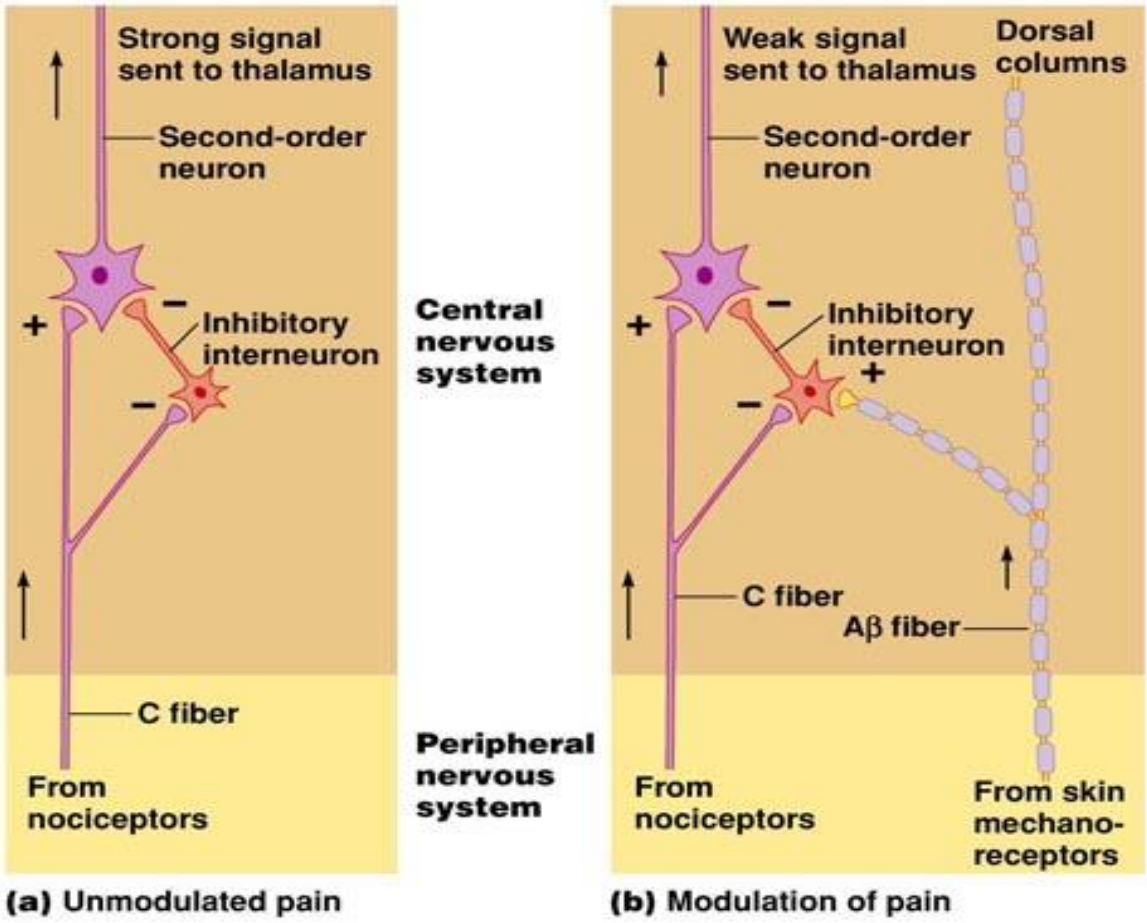


Figure 5.1-Pain gate mechanism

5.1.2 The Endogenous Opioid System

Another approach is opioid mechanism in which Aδ fibers are stimulated.

A delta (Aδ) fibers which respond favorably to a much lower rate of stimulation. In the order of 2 - 5 Hz, though some authors consider a wider range of 2 - 10Hz (Tousignant-Laflamme, practice, & 2017.).

Endogenous opiate (encephalin) is let out into the spinal cord which narrows the harmful sensory pathways hence alleviating pain which is how this mechanism works (Maeda et al., n.d.).

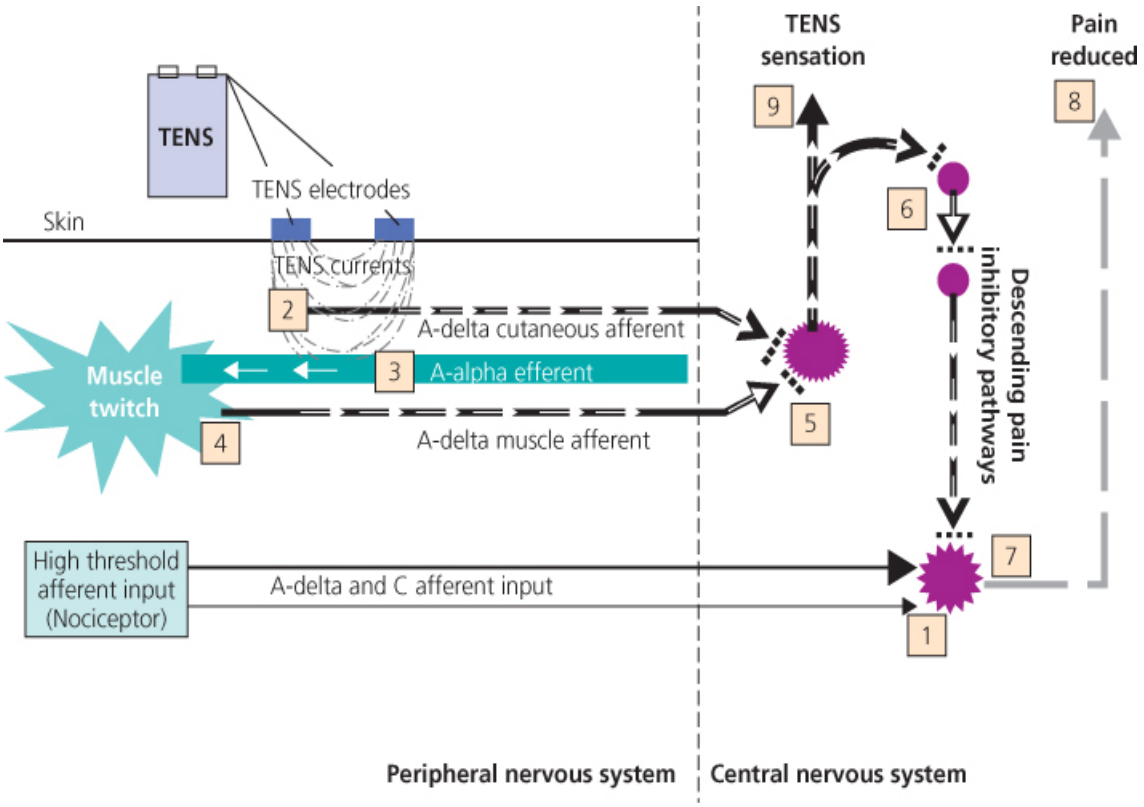


Figure 5.2-Endogenous opioid mechanism

Sensory peripheral nociceptive shows motion (1) Excited neurotransmitters are discharged which leads to motion in secondary nociceptive transposal cells in CNS (2) Inhibitory neurotransmitters which inhibit activity of secondary nociceptive transmission cells (4) are discharged by the activation of large-diameter harmless afferents by TENS (3). The inhibited nociceptive input to the brain causes the pain to be reduced (5). The activity caused by TENS in the central nervous system causes electrical paranesthesia (6) (Kalra, Urban, Experimental, & 2001.)

5.2 Efficacy of Burst TENS

Burst mode stimulates both nerve types simultaneously in which around 100Hz are discharged at 2.3 bursts per second

In this case, the higher frequency stimulation output (typically at about 100Hz) is disturbed (or burst) at the rate of about 2 - 3 bursts per second.

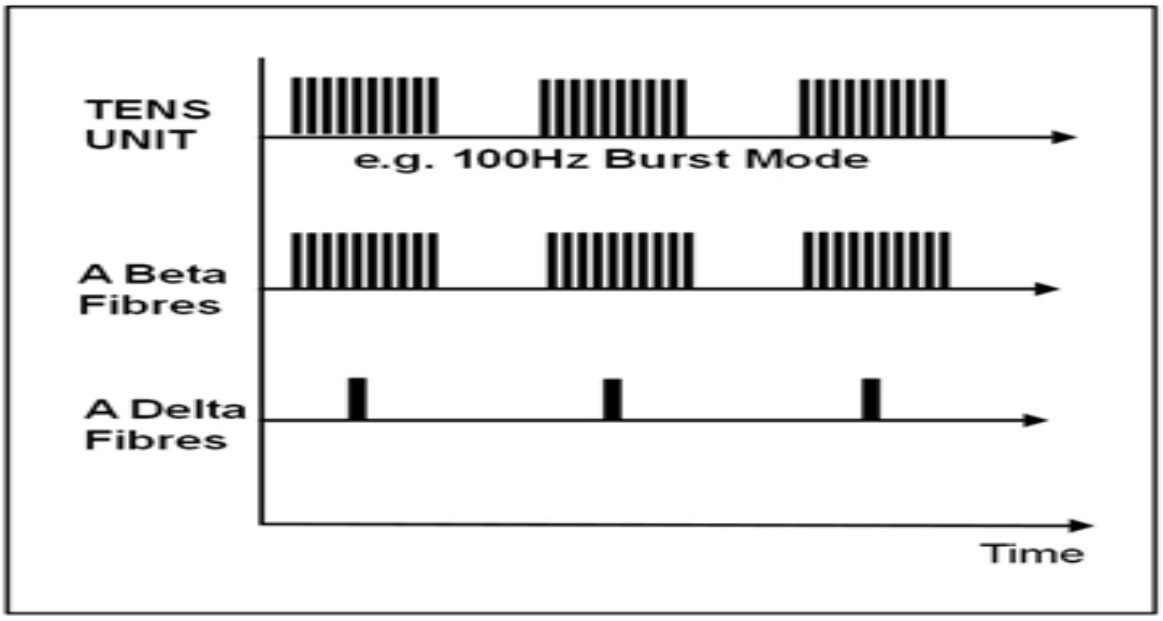


Figure 5.3-Burst- Transcutaneous Electric Nerve Stimulation

100Hz are discharged on switching the machine on which in turn excites Aβ fibers thus implementing the pain gate mechanism due to which each burst excites the Aδ fibers, and puts the opioid mechanism in place (Liebano et al.).

5.3 Limitations

Since TENS is ineffective on conditions such as lower back pain due to the lack of proper study designs and samples, it is necessary to continue testing it on larger groups of patients(J. M. DeSantana et al., 2008).

The successful use of TENS on individual pain conditions, such as lower back pain, is still argued, most likely because of ineffective study designs and small sample size. Thus, continued research of TENS mechanisms amongst adequately characterized patient populations is highly important(J. M. DeSantana et al., 2008)

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5.4 Conclusions

Transcutaneous Electric Nerve Stimulation (TENS) combined with heat and exercise plays a game-changing role in pain management and therapy.

Burst- TENS lessens the intensity of pain much better than routine therapy (heat and exercise).

TENS physiotherapy is safe, inexpensive and patient friendly. It has no side-effect compared to pharmaceutical intervention that is ridden with adverse effects.

Multiple strategies can be used to prevent resistance to repeated TENS therapy. Trials and experiments have been done to try to accurately pinpoint the place where TENS needs to be applied so that pain can effectively be reduced. To implement TENS, it is necessary to keep in mind and control the intensity at which the treatment is carried out (J. M. DeSantana et al., 2008).

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