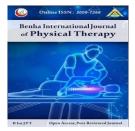
Benha International Journal of Physical Therapy



Online ISSN: 3009-7266

Home page: <u>https://bijpt.journals.ekb.eg/</u>

Original research

Immediate effect of transcutaneous electrical nerve stimulation on muscle tone in children with spastic cerebral palsy: a pilot study.

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Article history: Submitted: 01 -01-2024 Revised: 14-01-2024 Accepted: 18-01-2024

Abstract

Background: As spasticity in cerebral palsy is the major restriction in the rehabilitation process and the main cause of limb range limitations and joint contractures, we try to follow the pathway of spasticity and make a change from the origin by using a physical agent and trying its effect on muscle tone. **Purpose:** This study aims to look into how transcutaneous electrical nerve stimulation (TENS) affects children's calf muscle tone immediately following application. Methods: A pilot study of ten children was performed to determine the sample size needed for the randomized control trial. Subjects were divided into two groups: the study group received TENS, and the control group received a sham current. Each subject received TENS on one limb and received the sham current on the other limb at the same time. Muscle tone and range of motion were measured before and after the application of high TENS using a goniometer for measuring range of motion, electromyography, and a modified Ashworth scale for measuring muscle tone. Results: There was a significant increase in the ROM of the study group post-treatment in contrast to the control group's (p < 0.001). There wasn't a significant variation in spasticity and H/M ratio between the study and control groups after the intervention (p > p)0.05). **Conclusion:** The current study provides promising results to prove that there is an effect on the range of motion and muscle tone after applying high TENS. The authors also stand on the sample size for the randomized control trial.

Keywords: Electromyography (EMG); Modified Ashworth Scale (MAS); Range of motion (ROM); Transcutaneous electrical nerve stimulation (TENS).

Introduction

After a brain injury, a condition known as spasticity affects motor function. In regard to the research, spasticity is defined that elevated exteroceptive reflexes, stronger tendon reflexes, higher muscle tone, and pathological reflexes are all examples of this. Spasticity becomes a challenging issue when it crosses a specific threshold, and a neurological rehabilitation team should handle it. The second level involves physical techniques and medical care¹, spasticity causes a velocity or speed dependent rise in opposition to passively movement, which manifests as muscles hyper-tone and tight².

MAS is a grading system for spasticity, can be used to assess spasticity subjectively, and

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electromyography (EMG), an electrophysiological reference, can be used to examine it objectively. EMG is a commonly used instrument for evaluating the health of the peripheral nervous system. Blink reflexes, the F waves or H waves, which are induced by single or repeated stimulus uses a surface electrode to record or needle, are examples of reflex reactions that can be used to accomplish this^{3,4}.

Electrical stimulation used for therapeutic purposes, such as TENS, neuromuscular electrical stimulation, and functional electrical stimulation (FES) (NMES) and as well as strengthening, casting, tendon lengthening, dorsal rhizotomy, medications and muscle or nerve blocks are some of the management techniques for spasticity^{5,6}.

Spasticity treatment using transcutaneous electrical nerve stimulation (TENS) is uncommon. When in comparison with pharmacological TENS is a noninvasive, therapy, easily implementable approach with few side effects, no drug interactions, little possible toxicity, and lower long-term costs. In addition to having systemic adverse effects like liver damage, nausea, disorientation, and muscle weakness, baclofen and related medications have a limited ability to relax muscles. TENS may therefore be used in place of or in addition to medicinal treatment if sufficient improvement in spasticity is achieved with it¹.

TENS has been utilized to address spasticity resulting from spinal cord injuries and other lower motor neuron lesions. It has shown tremendous results in the management of tone and the enhancement of functional mobility⁷, although it is yet unknown how TENS might be affecting spasticity and movement control given that distinct spasticity patterns might emerge from different spasticity processes depending on the location of the lesion⁸. However, there are variability in stimulation patterns, measurement approaches, application techniques, and time of evaluation. The parameters of TENS application are variable among studies, but the most common is using high TENS, which is more preferred^{1,9-11}.

The main goal of our research is to identify whether TENS has an impact on spasticity in upper motor neuron lesions, such as cerebral palsy, and whether this impact is sufficient to justify using this tool in place of other spasticity management techniques and prescription medications.

Methods

Study design:

This research was done as a pilot study made on ten children with the same criteria. Children was divided into two groups to be compared: the control group as well as the study group. Within the same subject, the application was applied in one limb and the sham current in the opposite lower limb to obtain a clear result in the same case.

Participants:

Ten cases with spastic diplegic cerebral palsy took part in this research of both genders, they were chosen from Tanta City's El-Menshawy Public Government Hospital. Adhering to the official guidelines and getting the parents' consent, and describing the purpose and methodology of the research.

The following criteria determined which Cases are included in this study: Cerebral palsy, spastic diaplegia, their ages aged between three and ten years, both genders are involved. The MAS classified the subjects' muscle tones as mild to moderate (1 and 1+ for mild and 2 for moderate).

If the children met any one or more of the following criteria, they were excluded: Children who had experienced seizures in the past, were unable to lie prone for any reason, MAS is more than 2, and were unable to feel pain or under the effect of injections like Botulinum toxin BOTOX. *Procedures:*

modified Ashworth The scale (MAS) evaluation was carried out with children lying supine on an assessment bed. Dorsiflexing the ankle joint passively while the knee was extended and in a neutral posture, the degree of spasticity was determined. The 6-point MAS was used to evaluate and rate the resistance experienced throughout the exercise, with values score between 0 and 5, where joint stiffness is represented by 5 and no resistance by 0. A non-examinermaintained stability of the unexamined limb during the evaluation. Before and after the TENS application, the physiotherapist took two measures of the lower limb.

A non-examiner kept both lower limbs extended while the children were comfortably supine on the assessment bed, stationary arm of goniometer was paralleled to lateral side of fibula, and movement arm was paralleled to the lateral side of the fifth metatarsal. Goniometer's center should be over the lateral malleolus of the fibula. Passive manipulation of ankle was used in order achieve end range of dorsiflexion. Movement arm in parallel to lateral aspect of fifth metatarsal bone was the next step. Angle of ankle joint as measured by the goniometer was recorded. For every measurement, the researcher took two ROM readings before and after TENS application.

The H maximum amplitude / M maximum responses were recorded using the Cadwell Sierra II Wedge EMG system (CADWELL®, USA). The cases were comfortably positioned in a prone position. Eight equal divisions between the popliteal fossa and the medial malleolus were marked with a tape measure and pen after the skin had been cleaned. Every stimulation made use of two reusable surface electrodes. While the reference electrode was placed near the Achilles tendon on the last division, the active electrode was placed on the sixth division. Between the active electrode and the popliteal fossa on the third division, a ground electrode was positioned. A bipolar electrode connected to an electrical stimulator with bipolar EMG.

A licensed physiotherapist assessed the level of spasticity in the study participants' calf muscles using the MAS and Maximum amplitude of Hreflex and maximum amplitude of M-wave (HA Max/MA Max ratios).

The EMG device was configured to produce rectangular stimulation pulses with a width of one millisecond at 0.1 Hz. Twenty times, the stimulation was applied. The first time, the intensity was set at 9.5 mA, and it was increased by 0.5 mA increments until it reached its maximum of 19.0 mA. The sweep speed and sensitivity were set at 10 ms/D and 5 mV/D, respectively. An M-wave response and an H-reflex were elicited by each of the 20 stimulations, and they were all recorded. Both before and after TENS, the left and right calf muscles' H-reflex and M-wave responses were measured.

Following preliminary evaluations, an asymmetrical biphasic square pulse was produced using the TENS EV906 (Taiwan) gadget, which is a non-invasive, portable two-channel electrode attached to rubber electrode pads. An alcoholbased cleaning towel was used to cleanse the skin before the electrodes are implanted. Electrodes were placed over the calf muscle three fingers apart proximally the negative electrode, and distally the positive electrode. For this to be done, children were placed on the evaluation bed in comfortable prone positions. Using a frequency of 100 Hz and a pulse width of 200ms, all children received traditional TENS treatment for 30 minutes¹. The H/M ratio and MAS will then be used to reassess for the calf muscle, and the goniometer was used to measure the angle of ankle dorsiflexion. After arriving at the evaluation unit, children were given at least 10 minutes to rest before the procedures started.

The control group had a sham current on the other lower limb with measuring the same variables before and after application.

Statistical analysis:

The ages of the groups were compared using an unpaired t test. An analysis utilizing chi-squares was conducted to evaluate the gender distribution between the groups. The paired t test was used to compare ROM and the H/M ratio between the preand post-treatment periods, and the Wilcoxon signed ranks test was used to compare spasticity grades. The ROM and H/M ratio were compared between groups using the unpaired t test, and the spasticity grades were compared using the Mann-Whitney test. At a significance level of p < 0.05, all statistical tests were performed. Each and every statistical analysis was performed using SPSS for Windows, version 25.

Results

Subject characteristics:

The distribution of sex and age did not significantly differ between the groups (p > 0.05). Table 1 shows the subject characteristics of the study and control groups.

	Study group	Control group	t- value	p- value
Age (years), Mean ± SD	6.6 ± 1.96	6.55 ± 1.83	0.06	0.95
Sex, n (%)				
Girls	4 (40%)	4 (40%)	$(\chi^2 = 0)$	1
Boys	6 (60%)	6 (60%)	0)	

Table 1: Basic characteristics of participants

SD, standard deviation; χ^2 , Chi squared value; p-value: probability value.

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Effect of treatment on spasticity, ROM and H/M ratio:

Study group : The study group's spasticity grades significantly decreased after treatment compared to before (p < 0.01). The study group's ROM increased significantly after treatment when compared to before (p < 0.01). The H/M ratio did not change significantly (p > 0.05). (Tables 2,3)

Control side: The control group's spasticity grades, ROM, and H/M ratio did not change significantly (p > 0.05). (Tables 2,3)

Comparison between study and control groups: After treatment, the study group's ROM significantly increased in comparison to the control group (p < 0.001). After treatment, there was no discernible difference in the study and control groups' levels of spasticity or H/M ratio (p > 0.05). (Tables 2,3)

Table 2. Mean values of ROM and H/M ratio preand post treatment of study and control groups

	Study group	Control group						
	mean ± SD	mean ± SD	MD	t- value	p-value			
ROM								
Pre treatment	6.1 ± 12.69	5.7 ± 2.98	0.4	0.09	0.92			
Post treatment	20.3 ± 6.89	6.2 ± 3.25	14.1	5.84	0.001			
MD	-14.2	-0.5						
t- value	-3.92	-1						
	<i>p</i> = 0.003	<i>p</i> = 0.34						
H/M ratio								
Pre treatment	0.62 ± 0.34	0.54 ± 0.25	0.08	0.54	0.59			
Post treatment	0.46 ± 0.18	0.56 ± 0.25	-0.1	- 1.02	0.31			
MD	0.16	-0.02						
t- value	1.77	-1.07						
	<i>p</i> = 0.11	<i>p</i> = 0.31						
SD Standard deviation MD Moon differences								

SD, Standard deviation, MD, Mean difference; p-value, level of significance **Table 3.** Median values of MAS pre and posttreatment of study and control groups

	Study group Median (IQR)	Control group Median (IQR)	U- value	p-value
MAS				
Pre treatment	3 (4, 2.75)	3 (3.25, 1.75)	37	0.29
Post treatment	2 (3, 1.75)	3 (3.25, 1.75)	38	0.34
Z- value	-3	0		
	<i>p</i> = 0.003	<i>p</i> = 1		

IQR, Interquartile range, U value, Mann-Whitney test value; Z- value, Wilcoxon signed ranks test value; p-value, level of significance.

Discussion

TENS is an electrical stimulation approach that aims to activate the opioid system or activate the pain gate mechanism in order to reduce specific types of clinical pain. The various TENS application techniques connect to these many physiological pathways; also, TENS is a noninvasive method that has fewer side effects than pharmacological therapy¹².

By stimulating (exciting) the sensory nerves, the TENS unit aims to trigger some of the body's own pain-relieving processes. Considering the two primary the alleviation of pain systems that can be triggered—the mechanism of Pain Gate and the Endogenous Opioid System—it may be easier to comprehend how TENS works¹³.

TENS is thought to reduce spasticity through a number of different processes, including 1) activation of large diameter afferent nerve fibers that modulate aberrant interneuron activity in diverse spinal segments^{14, 15}. 2) Constant sensory peripheral nerve fiber stimulation, which leads to decreased corticomotor neuron excitability and insensitivity to extended central excitation¹. 3) Unmasking or remodeling of somatosensory-motor cortical connections¹⁶. 4) Stimulation of central nervous system plasticity^{17,18}, or 5) a combination of the aforementioned¹⁹.

Another study has been mentioned that using TENS for 45 minutes may reduce the ordinarily heightened stretch reflex excitability that comes along with spasticity, so the cause and mechanism may be unclear but clinically we have found an effect.

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It's important to know that electrophysiological just the alpha motor neuron activity-related variables weren't nearly equally essential as clinical factors 1. So, we measured the range of motion and modified Ashworth scale to gain a clinical finding about the real effect not only depending on EMG findings.

After applying high Tens with parameters of 100 Hz and pulse width 200µs for 30 minute in the calf muscle of one lower limb there was a clearly decrease in the range of motion for the dorsiflexion movement and also the muscle tone using MAS, the change is not only on the application side but also the other side shows effect on range of motion and muscle tone, so we recommend to apply the control group (sham current) in a separated time for the same subject to ensure that we obtain a clear results.

After the pilot study, we gained a great result in MAS and ROM measurements, and after sample size calculation, we need sixty children that will be divided in two groups, and to be accurate, we had to make a comparison between two groups within the same subject at a separate time.

The results are immediately after the application and shows that there is a significant effect in before and after application for ROM and MAS but in H/M Ration After treatment, there was a no significant difference.

So, by applying high TENS application for 30 min, we obtain a great result electrophysiological and in the clinical aspect that may open the door for functional movement improvement and According to a study, it might be used in alongside medical treatment for spasticity¹. We obtain great result for a non-invasive tool that are not commonly use.

Limitations

the subjects need to be more specific close in age and tone level, we don't have a wide reference range on this study for evidence based practice to TENS application on cerebral palsy children so we choose a wide subject range, also we need to measure H-latency to stand on the effect of stretch effect, we can't apply it due to the wide sample size that give a variable reading and will affect the statically findings so if we need to measure H-Latency we need a more specific sample size. We also recommend more studies for the long term of this effect, its dose and when it last especially it is not applied before in cerebral palsy children.

Conclusion

We concluded that there is an effect in the range of motion and muscle tone after applying high TENS with a promising result for a cheap, non-invasive and easily applied tool, we have to stand on the long-term effect and dose to be compared with other spasticity management approaches, we also stand on the sample size needed for the randomized control trial.

Source of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical approval

The study was carried out in accordance with ethical standards for the operation of the devices used, and it was approved by the faculty of physical therapy Cairo University's ethical and protocol review committee 012/004377, this trial is registered in clinicaltrials.gov ID NCT05649254.

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