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EFFECT OF TRANSCRANIAL LASER ON SOMATOSENSORY INTEGRATION IN PATIENTS WITH NONSPECIFIC NECK PAIN: RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Introduction: Nonspecific neck pain is a frequent cause for adults to consult health care providers. Therefore, the physical therapist should always seek the most effective intervention(s) within the wide spectrum of treatments available, so this study was conducted to examine the effect of transcranial laser on somatosensory integration in nonspecific neck pain patients.

Methods: Thirty-two male subjects suffering from non-specific neck pain participated in the current study. They were randomly assigned via a balanced stratified assignment. The experimental group (N=16) received trans-cranial infra-red laser (50mw, 90 snm pulsed mode, and 1.2 J/cm²) over sensory cortex whereas, the control group (N=16) received placebo laser. The assessment of N30 and P22-N30 components of somatosensory evoked potentials (SEPs) were done before and immediately after treatment session for both groups.

Results: There was a statistically significant difference between groups regarding N30 peak of SEPs after a single trans-cranial laser session (p=0.0062) with no significant difference between pre and post-treatment data in the experimental group (p=0.0803) and control group (p=0.5577) with a percentage of change (-2.38%) and (1.009%) respectively. In addition, post-treatment results revealed no statistically significant difference between groups regarding an a P22-N30 component of SEPs (p=0.0933).

Conclusion: According to the parameters used in the study, it was concluded that trans-cranial laser did not affect somatosensory integration in nonspecific neck pain patients.

Keywords: Transcranial, laser, somatosensory, integration, neck, pain.

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INTRODUCTION

Neck pain is a common painful musculoskeletal condition that affects individuals worldwide. Prevalence data suggest that neck pain can affect children and elderly alike. Its incidence is ranging from 6% to 22% and up to 38% of the elderly population [1]. There is wide variability in identifying neck pain despite its high incidence. This is due to the presence of both physical and psychological factors predisposing cervical spine pain. So, as a result of multiple factors presenting neck pain and the inability to precisely identify the cause of its symptoms [2], the term nonspecific neck pain has been assigned to any undiagnosed symptomatic disorder of the cervical spine [3].

Neck pain incorporates a significant result on individuals' health quality of life and on society as a whole. So, higher management approaches in medical aid required to be developed to stop patients from developing chronic pain and disability [4]. It is evident that the neuromuscular and proprioceptive functions impaired in patients with back and neck ache which give areas on why what starts in the form of a restricted range of motion and/or mild pain becomes chronic as the neck is joined to the upper limb neurologically and biomechanically. A systematic review in 2012, by Haavik-Taylor, and Murphy [5], bestowed proof suggesting that altered sensory process from areas of joint dysfunction could lead to faulty somatosensory integration attribute to central neuroplastic changes.

The label somatosensory reflects all the sensory information, motor information, central integration and processing elements that sustain stability in the postural control system throughout intrinsic motor-control properties. So, somatosensory impairment can arise from altered cervical afferent input [6].

There is a great proof pointing to the idea that subjects with chronic pain might develop anatomical alterations in brain areas responsible for cognition and emotional modulation of pain, like dorsolateral and medial prefrontal cortex, the anterior cingulate cortex and the insula. Moreover, the results of the previous studies which used in vivo proton magnetic resonance spectrometry revealed rise in glutamate and/or reduction of N-acetyl aspartate in frontal cortices in subjects with a fibromyalgia and chronic backache; such results agreed that reduced grey matter might be related to possible excitotoxicity in patients with chronic pain [7,8].

Early somatosensory evoked potentials (SSEPs) as an objective modality offer a mechanism for investigation of alterations in somatosensory integration areas of the brain. It had been disclosed that N30 component of SSEPs peak is produced in post-central gyrus as primary sensory cortex is connected to a complex subcortical and cortical circuit connecting the pre-motor areas, primary motor cortex, basal ganglia, and thalamus. Therefore N30 peak is assumed to assess somatosensory integration [9,10,11,12,13].

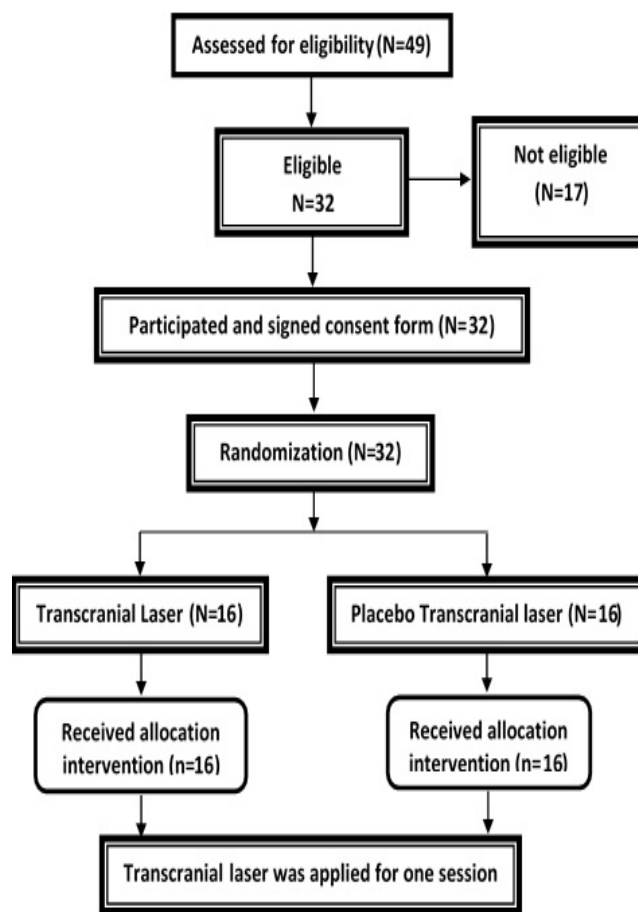
There is a growing body of knowledge concerning the effect of transcranial laser therapy (TLT) on cognition [14], attention bias [15], depression [16], traumatic brain injury [17], and stroke [18], and considered as a promising non-invasive modality for neuromodulation that can

produce biochemical changes including enhancing adenosine triphosphate synthesis by mitochondria, increase reactive oxygen species and intracellular calcium, nitric oxide release, and might include inhibition of apoptosis in ischemic penumbra and improvement of neuro recovery mechanisms [19]. But, there is a gap of knowledge regarding its effect on somatosensory integration. So, the current study was designed to examine the effect of transcranial laser on somatosensory integration in nonspecific neck pain patients.

METHODS

The current research was performed in Faculty of physical therapy, Cairo University, from April 2016 to August 2017 to examine the effect of transcranial laser on somatosensory integration in nonspecific neck pain patients.

Design of the study: prospective, randomized, placebo, controlled trial.



Flowchart 1: Diagram of the study design

Subjects:

Thirty-two male patients were selected and assigned randomly after signing a consent form before data collection. The age ranges from 20 to 30 years. Group A (experimental group): 16 patients with their mean age (25.13 ± 3.1). Group B: (control group): 16 patients with their mean age (26.88 ± 1.63). Exclusion criteria were hemorrhagic stroke patients, thrombotic and embolic stroke patients with probable vascular damage [20], sustained hyperglycemia or hypoglycemia ($>three$ hundred or $<sixty$ mg/dl), sustained hypertension (systolic $>two$ hundred and twenty mmHg or diastolic $>one$ hundred and forty mmHg), hypotension (systolic $>eighty$ mmHg or diastolic $>fifty$ mmHg),

vascular disease, intravenous or intra-arterial thrombolytics, epilepsy, multiple sclerosis, dystonia, abnormal peripheral nerve function, and skin infection [21]. Patients should have a history of chronic nonspecific neck pain > three months and their body mass index between 18 and 25 kg/m². Ethical approval was obtained from the institutional review board Faculty of Physical therapy, Cairo university with number T. REC/012/001178 and registered with pan african clinical trial registry with number (PAC-TR 20181001399154).

Instrumentation:

Two types of instrumentation were used in this study:

1. Computerized electromyography (EMG) device.
2. Laser therapy unit.

(1) Computerized electromyography (EMG) device:

Deymedtru trace flexi cart computerized electromyography system, manufacturer Deymed diagnostic s.r.o, country of manufacturing was the Czech Republic, and the model of the device was true trace EMG CL4 its volt was 220-250 V and 50-60 Hz.

(2) Laser therapy unit:

Medical Italia LIS laser therapy unit was used, manufacturer EME physio, country of manufacturing was Italy. It is a probe Infra-Red (IR) laser with one diode (MLA1/50) of 50 mW for 905 nm. It has the following technical parameters; its volt was 230V, 50-60Hz, pulsed operating mode 10-100%, an automatic contact sensor, and automatic dose calculation. The pulse frequency can be adjusted between 200 – 10000 Hz with pulse duration 100 nsec.

PROCEDURE

Measurement of somatosensory evoked potential:

The position of the patient: good relaxation of the patients is vital due to the very small size of the cortical potentials. Therefore, the patients were instructed to sit still while remaining quiet with their eyes closed; room's lights were turned off.

Skincare under stimulating electrodes; methylated alcohol was used to carefully wash the skin overlying the median nerve and then dried using dry clean cotton wool. This action was repeated until hyperemia of the skin occurred aiming to reduce skin resistance. Cautions were taken to avoid breaking or abrading skin under the stimulating electrode. When the impedance -across the recording electrodes preparation sites- was between 1,000 and 5,000Ω, abrasion is accepted and considered sufficient [22].

Parameters of SSEPs stimulation:

The stimuli were electrical square pulses, with 1ms pulse duration, and 2.47 Hz frequency, the stimulating electrode was Ag/AgCl ECG skin electrodes with resistance less than 5,000Ω. The median nerve was stimulated two: three centimeters from the distal crease of the wrist, between tendons of Flexor pollicis longus and Palmaris longus with anode placed proximally, and cathode distally. The frequency, 2.47 Hz is optimum for N30 and didn't lead to a decrease in SEP peak. For every patient, the amplitude of stimuli used was the motor threshold that is the most lower amplitude of stimuli that produces a noticeable contraction of abduc-

tor pollicis brevis muscle [23,24].

Recording parameters:

Recording electrodes were placed on the frontal Rossi site (six centimeters anterior and two centimeters contralateral to Cz) [25] according to (IFCN) guidelines [26]. The two recording electrodes were two millimeters gold cup EEG electrodes with an impedance less than 5,000Ω and the ground electrode placed on patients' forehead. SSEPs signal was amplified (gain 10,000), filtered (0.2–1000 Hz) and stored on a computer. Far-field potentials demand a higher number of standard sweeps. The standard waveform was displayed in an analysis window from which amplitudes of the specific waveforms were measured [27].

N30 and P22-N30 components of SSEPs were measured before and after transcranial laser application according to the IFCN guidelines [9]. The following SSEPs components; N30, and P22-N30 complex were identified and analyzed.

Experimental Protocol:

The patients were asked to attend one session of TLT. They were diagnosed by an orthopedic physician. All patients were screened for contraindications of TLT. One baseline SEP trial was carried out before treatment through stimulation of the median nerve and repeated immediately after transcranial laser application.

For treatment purpose, Medical Italia LIS laser therapy unit (230V, 50Hz) was used. It is a point probe Infra-Red (IR) laser delivers 50 mW for 905 nm. It has the following technical parameters, pulsed operating mode 10-100%, an automatic contact sensor, and automatic dose calculation. The frequency can be adjusted between 200 – 10000 Hz.

Application of transcranial laser: The protocol of lamp and his colleagues in 2007 and Zivin and others in 2009 was followed using laser probe which was applied over the entire surface of the head according to 10/20 electroencephalographic system on sensory cortex for 4 minutes at every point. Infrared Laser power of 50mW, transmitting an energy density of 1.2 J/cm², and pulsed mode 100% [19,28], with a frequency of 1000 Hz and a pulse duration 100 nsec. The transcranial laser was applied once to study its immediate effect on somatosensory integration.

The patient was seated in comfortable sitting position. Patient and therapist wore protective glasses to avoid the possibility of damage to retina if the laser beam enters through the lens of the eye and onto the retina. The laser probe is applied at a right angle to patient's skin.

Statistics:

Statistical analysis was done using SPSS, version 20.0 for Windows; SPSS Inc., Chicago, Illinois, USA. Descriptive statistics for patients' physical characteristics and the dependent variable were calculated as mean, and standard deviation. Paired t-test was conducted for comparison between the before and after treatment values in the same group. Unpaired t-test was conducted for comparing the results between groups. The alpha level of significance (α) was set less than 0.05.

Sample size:

Power analysis of a pilot study was used for sample size

estimation. In the pilot study, ten articpansing Lapist should5). patients were divided into two equal groups, study group (mean 28.452 and SD 3.5757) and control group (mean 31.64 and SD 1.8515) two-tailed hypothesis, alpha =0.05, power =80%. G-power test determined the sample size of each group with a total sample size of thirty-two patients.

Data Collection:

Patients were acclimated with the electrical stimulation required to provoke SSEPs while the determination of motor threshold, decreasing the possibility of rejection of any sweeps during data collection of SSEPs components. The regarded patient`s age and body mass index had been collected in information sheet before entry to study. Paired t-test and unpaired t-test were conducted for comparing values of dependent variables within and between groups respectively with (α) set less than 0.05.

RESULTS

Patients` physical characteristics were illustrated in table (1). The unpaired t-test revealed nonsignificant differences between both groups concerning age, and body mass index.

Table 1: physical characteristics of patients in both groups

Variables	Experimental Group	Control Group	Comparison	
	Mean ± S.D	Mean ± S.D	t-value	Significance
Age (Years)	25.13±3.1	26.88±1.63	2.0014	0.0545
Body mass index (Kg/ m ²)	22.194±1.886	23.019±1.749	1.2829	0.2094

Significant at an alpha level less than 0.05.

(1) N30 peak of somatosensory evoked potential results:

As shown in tables (2and 3), unpaired t-test revealed a statistically significant difference between groups regarding N30 peak of SSEPs after a single trans-cranial laser session (P=0.0062). Whereas, paired t-test revealed no significant difference between pre and post-treatment data in the experimental group (P=0.0803) with a percentage of change (-2.38%) and control group (P=0.5577) with a percentage of change (1.009%).

Table 2: unpaired t-test of N30 peak SSEPs (ms) for both groups:

Unpaired t-test	Experimental Mean±SD	Control Mean±SD	T value	Significance
N30 pre	29.7244±2.4416	31.006±2.367	1.5078	0.1421
N30 post	29.0169±2.5579	31.319±1.798	2.9452	0.0062*

Significant at an alpha level less than 0.05.

Table 3: Paired t-test of N30 peak SSEPs (ms) for both groups:

Paired t-test	Mean± SD pre	Mean± SD post	T value	significance	Mean difference	Percentage of change
Experimental	29.7244± 2.4416	29.0169± 2.5579	1.8754	0.0803	-0.7075	-2.38%
Control	31.006± 2.367	31.319± 1.798	0.5996	0.5577	0.313	1.009%

Significant at an alpha level less than 0.05.

(2)P22-N30 peak results

Post-treatment results showed no statistical significant difference between groups regarding P22-N30 component of SEPs (P=0.0933), in addition to no significant difference between before and after treatment values in experimental and control groups with a percentage of change (-12.607%) in experimental group and (-1.1538%) in control group as presented in table (4and 5).

Table 4: Unpaired t-test of the P22-N30 peak of SSEPs for both groups:

Unpaired t-test	Experimental Mean±SD	Control Mean±SD	T value	significance
P22-N30 peak pre	1.64369± 0.74303	1.95± 0.7607	1.1522	0.2583
P22-N30 peak post	1.43647± 0.8539	1.9275± 0.7431	1.7351	0.093

Significant at an alpha level less than 0.05.

Table 5: Paired t-test of theP22-N30 peak of SSEPs for both groups:

Paired t-test (P22- N30 peak)	Mean ± SD pre	Mean± SD post	T value	significance	Mean difference	Percentage of change
Experimental	1.64369± 2.4416	1.43647± 0.8539	0.6717	0.512	-0.20722	-12.607%
Control	1.95± 0.7607	1.9275± 0.7431	0.5538	0.5878	-0.0225	-1.1538%

Significant at an alpha level less than 0.05.

DISCUSSION

The laser is considered a promising noninvasive modality for neuromodulation. There are numerous investigations examined its impact for cognition [29,14], attention bias [15], depression [16], traumatic brain injury [17], and ischemic stroke [18]and found to be effective noninvasive modality capable of improving the metabolic activity of neurons as a result of increased oxygen consumption and adenosine triphosphate synthesis. Also, the motor function was significantly improved after application of LLLT in the early stage of familial amyotrophic lateral sclerosis [18].

The current study was designed to examine transcranial laser efficacy on somatosensory integration in nonspecific neck pain patients. Findings of this study revealed a significant difference between groups regarding N30 peak of SEPs (P=0.0062) with the percentage of change -2.38%, and 1.009% in experimental and control groups respectively. Whereas, there is the non significant difference between groups regarding P22-N30 peak of SEPs (P=0.093).

Regarding N30 peak of SEPs results, findings revealed a significant difference between groups (P=0.0062) with a small percentage of change -2.38%, and 1.009% in experimental and control groups respectively in addition to the nonsignificant difference between before and after treatment data of the two groups. This decrease of N30 cannot be considered as an improvement as this result is inconsistent with the result of a previous study examined the effect of TLT on peripheral nociception. They found to decrease in the conduction of painful stimuli owing to the decreased frequency of action potentials [30] taking into consider-

ation that latency gradually increases as the sensory nerve conduction velocity decreases [31].

Likewise, Taylor and Murphy in 2008 investigated alterations in intrinsic inhibitory interactions within the sensorimotor system after spinal manipulation session of dysfunctional cervical spines. Their study revealed no significant difference in N30 peak along with suppression of P22-N30 component of SEP [32].

The first explanation for the nonsignificant difference between groups regarding dependent variables may be attributed to no current protocols were found in a healthy population, in which the parameters (intensity, power, duration, number of sessions, and fluency of the laser light) of the stimulation are settled. Therefore, there is no general agreement regarding parameters that should be selected for stimulating the intact cortex in order to efficiently stimulate the target cortical area by near-infrared laser [33]. Similarly, the effects of transcranial laser application take time to start and it is possible that duration of tissue extraction was not enough to detect biochemical changes as well as the dosage [30].

Regarding the parameters, the review of the literature revealed that, there were contradictory results concerning the parameters of TLT as Pires de Sousa and others in 2016 applied transcranial laser in animal models with the following parameters (810 nm laser, 300 mW/cm², 7.2 or 36 J/cm²) to study its effect on peripheral nociception [30]. They found a decrease in metabotropic glutamate receptors in the tissue, leads to a reduction of conduction of painful stimuli due to the decreased action potentials' frequency. Similarly, Salehpour and his colleagues used laser treatments for six weeks at wavelengths of 660 and 810 nm at 8 J/cm² which have potential to ameliorate aging-induced mitochondrial dysfunction, apoptosis, and cognitive impairment. On the other hand, same wavelengths at the fluency of 4 J/cm² had a poor effect on the behavioral and molecular indexes in the aging model [16].

In 2016, Hwang and others used transcranial low level laser therapy on two sites of forehead (total duration 8 min, 1064 nm, continuous mode, 250 mW/cm², 60 J/cm² per site of 13.6 cm²) in combination with acute aerobic exercise and found that TLT is capable of improving cognition, recommending that TLT augments pre-frontal cognitive functions [34].

In line with the other researchers (Xuan et al., 2014) investigated the effect of transcranial laser in patients with traumatic brain injury. They used 810-nm laser delivering 18 J/cm² fluency and 25 mW/cm² and found TLT to be effective in improving neurological performance [35]. Similarly, (Konstantinovic et al., 2013) used (wavelength 905 nm, the frequency of 3 kiloHertz, the power density of 50mW/cm², and single dosage of 3J/cm²) in the 1st part of their study to examine if the transcranial laser could change motor cortex excitability. They mentioned that the most prominent motor evoked potential (MEP) inhibition was within 10–25 min after transcranial laser [36].

Laser irradiation produces neglected amount of heat without causing physical damage at the low power level was founded by (Schiffer et al., 2009). In their study, TLT had

been examined for its effect on depression. They recruited healthy subjects who received continuous near-infrared laser. The laser was delivered to the forehead using low-power laser diode (wavelength 1064 nm). The power density 250 mW/cm², as well as the cumulative energy density 60 J/cm² showed antidepressant effect [37].

Hesse et al., 2016 investigated efficacy of transcranial laser on alertness and awareness in patients with traumatic brain injury and severe disorders of consciousness. they stimulated the cortex of five subjects, four of them are chronic with unresponsive attentiveness or minimal awareness, and one patient subacute with a kinetic mutism, with the transcranial laser (785 nm, 10 mW/cm², continuous wave mode, 21 emitting diodes) for ten minutes every workday for 6 weeks. Their results supported that TLT had been found to improve the patients' alertness and awareness [38].

The second explanation for the nonsignificant difference between groups regarding P22-N30 may be attributed to that application of laser did not exert an analgesic effect as patients with neck pain had a significantly higher joint position sense error than healthy controls (De Vries and others in 2015) which in turn affects somatosensory integration [39].

In 1997, Tinazzi and others recruited 10 patients with a cervical disc prolapse compressing the C-6 nerve root and ten healthy age-matched controls. Unilateral radiating pain from the nerve root (C6) shows differences in SEP amplitude between impaired and unimpaired sides and between the impaired side and healthy controls. SEPs were recorded in a between-limb, and between-subjects design. Amplitudes of peaks N13, P14, N20, P27, and N30 were amplified remarkably in the extremity with the presence of pain. This explains that there is a positive correlation between the presence of pain and SEP amplitude [40].

(Pires de Sousa et al., 2016) Proved that TLT is effective in decreasing pain sensation all over the body in response to different forms of stimulation. Application of laser precisely over somatosensory cortex was reinforced by proof of photoneuromodulation of neuromarkers related to nociception. Pain reduction could be related to the biochemical alterations that take place due to photons' absorption. The release of prostatic acid phosphatase is regulated by adenosine triphosphate as its formation needs a sufficiency of energy. An increase in endogenous analgesic prostatic acid phosphatase could decrease the pain perception. The amount of Glutamate which is an excitatory neurotransmitter involved in nociception was remarkably high in the control group than in the groups received transcranial laser [30].

Limitations

There are several limitations of the study. The first one is the individual variability regarding the penetration depth of laser which is affected by the thickness of the skull and scalp that can be very different among healthy individuals, resulting in different penetration depths.

The second point is related to the transcranial application of laser in humans that the intensity of laser required for

triggering photo neuromodulation might be hurtful as laser intensity has to be sufficient to penetrate skull without rising the temperature of the brain. The third point is the inability to deliver laser to deep structures of the central nervous system while maintaining a low intensity at the cortical surface.

CONCLUSION

According to the parameters used in the study, it was concluded that trans-cranial laser did not affect somatosensory integration in patients with nonspecific neck pain

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Nil

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