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LETTER TO THE EDITOR

Efficacy of transcutaneous electrical nervous stimulation in patients with somatosensory tinnitus and cervicofacial myalgia

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To the Editor,

Tinnitus can be defined as the involuntary perception of a sound in the absence of an auditory stimulus. The pathogenesis originates in the brain, and tinnitus has been associated with a worsening of quality of life. In terms of diagnosis, it is defined as "subjective" or "idiopathic," if it cannot be detected by the examiner. It can be continuous or intermittent, its intensity can be stable or variable, and it can have a sensorineural or middle ear origin (1). The overall annoyance of tinnitus is a result of its characteristics and of the psychological make up of each individual patient (2). Several parts of the brain are involved in the representation of tinnitus and of the reactions to it. Treatments can be focused on reducing tinnitus (e.g. pills) or on reducing the reactions to the tinnitus (e.g. Counseling). Approximately 1–2% of the population in industrialized areas suffers from clinically relevant tinnitus (3, 4). Pezzoli et al. (5) suggested that among the types of facial pain, only myogenic pain is significantly related to tinnitus, although migraine may also have a role. Transcutaneous electrical nerve stimulation (TENS) is recognized as an effective treatment for chronic musculoskeletal pain. Although the neurophysiological mechanisms of TENS-induced tenderness reduction have not been fully defined, it is known that it activates supraspinal opioid receptors (6). When the electrodes are placed near the ear (at the level of the temporomandibular joint and close to the insertion of the masseter muscle), TENS seems to increase the activation of the dorsal cochlear nucleus by somatosensory stimulation and augment its role in auditory stimuli selection, possibly leading to a reduction of tinnitus intensity and frequency (7). There has been a lack of trials investigating the influence of TMD therapy on tinnitus. Previous studies have mainly focused on TMD therapy with occlusal splints, as well as selective grinding and laser therapy. Thus, the aim of this study was to evaluate the efficacy of TENS in effecting changes in quality of life, perceived tinnitus intensity, and audiometric and tinnitometric values, among patients with craniofacial myalgia and tinnitus with somatic modulation.

MATERIALS AND METHODS

The study sample was selected from a pool of 168 patients (45 males, 123 females, average age 42.08±20.4 years) consecutively assessed over an 18-month period, at the Department of Gnathology of the Dental School, University of Turin, Italy. The inclusion criteria comprised

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adults with cervicofacial myalgia (111 patients out of the initial 168) who also complained of persistent somatic tinnitus (27 patients out of 111) for at least 6 months (21 patients out of 27). The latter criterion was instituted in order to limit the potential bias associated with the physiological reduction of tinnitus intensity in the first 6 months after its onset.

The exclusion criteria included the following: hearing loss (a hearing loss of up to 20 decibels below the hearing threshold is still considered to be normal hearing, the aforementioned information has been added to the text); pregnancy; presence of either psychiatric, neurological, or rheumatological comorbidity; cardiological pathology; pathology or sequelae of a past pathology that affects the middle or inner ear; and risk of depression or anxiety disorder as assessed with the Hospital Anxiety and Depression Scale (HADS). Patients whose HADS score was 11 or higher were excluded, in accordance with the generally accepted cut-off for high risk depression/anxiety disorder (15 patients).

All subjects provided written informed consent to the inclusion of material pertaining to themselves, and acknowledged that they would not be identified via the paper. All subjects were fully anonymized. The study was approved by the local Ethical Committee (# 3742015), and conducted in accordance with the principles of the Declaration of Helsinki.

Primary and secondary outcomes were recorded at T0 and T1 (10 weeks of TENS treatment). The primary outcomes included tinnitus effects on quality of life [Tinnitus Handicap Inventory (THI) questionnaire], perceived tinnitus intensity, and audiometric and tinnitometric values. The 25-item THI questionnaire 26 evaluates the influence of tinnitus on quality of life, with each item being given a score of 4 (if the answer is yes), 2 (if the answer is sometimes), or 0 (if the answer is no). The maximum score is 100 points. Perceived tinnitus intensity comprises four individual components, with each being assessed with visual analog scale (VAS) consisting of a 100-mm horizontal line to be crossed between 0 and maximum bearable intensity and to be read using a ruler to quantify patient's perceived intensity. These comprise; perceived tinnitus volume (0 = absence of tinnitus, 10 = maximum intensity); patient anxiety level (0 = maximum serenity, 10 = maximum anxiety); state of mind (0 = maximum tranquility, 10 = maximum insecurity); and tinnitus tolerability (0 = absent, 10 = intolerable).

For the determination of audiometric values, audiological evaluation was conducted with pure tone audiometry performed in a soundproof booth at 5 dB intervals, with audiometer 455 Amplaid Audiometers (Amplifon, Milan). Tinnitometry was performed with the same machine to assess tinnitus intensity. The test was performed contralateral to the most affected ear. The initial pitch or frequency of tinnitus was determined by asking patients to indicate to the examiner when they realized that the sound presented was similar to their tinnitus frequency. Loudness was determined at the same frequency indicated by the patients as being similar to their tinnitus. The stimulus was presented with an initial intensity 10 dB below the patient's hearing threshold, and then increased in steps of 1 dB. The final intensity was recorded and subtracted from the individual hearing threshold to obtain each patient's level of sensation.

The secondary outcome of this study comprised: cervical tenderness score (CTS) and pericranial tenderness score (PTS) on palpation; perceived muscle pain intensity VAS; and range of movement (ROM). For the PTS, the pericranial muscles examined were the masseter, lateral pterygoid, medial pterygoid, temporalis at the mandibular insertion, and temporalis at the cranial insertion. For the CTS, assessments were performed for the sternocleidomastoid (belly and cranial insertion), trapezius, and sub-occipital muscles. Tenderness on palpation was scored in each location from 0 to 3 (0 = normal tone; 1 = mild; 2 = moderate; 3 = severe tenderness). Pericranial and nuchal muscles were palpated (i.e., small rotational movements with pressure) with the second and third finger. The other cervical muscles were pinched delicately. The palpation of each site lasted 3–4 seconds. The scores for pericranial muscles and cervical muscles were added separately, and the total obtained was divided by the number of sites examined. Thus, a PTS and CTS (range 0–3) was calculated for each patient.

The assessment of perceived muscle pain intensity comprised three components, with each being assessed with VAS. These included the maximum intensity of muscle pain (0 = absent, 10 = intolerable), average intensity of muscle pain (0 = absent, 10 = intolerable), and intensity of muscle pain at the time of the visit (0 = absent, 10 = intolerable). A tongue blade was held against the maxillary anterior teeth, with the mesioincisal embrasures between

the mandibular central incisors being used as a reference point to record maximum right and left laterotrusion, maximum protrusion, and maximum opening.

Home therapy with TENS (NeuroTracTM TENS, Verity Medical Ltd., Farley Lane, Braishfield, Hampshire, UK) was administrated according to the protocol published by the University of Turin (8) (Figs. 1 and 2), which specified the following properties and settings: double channel TENS with individually isolated circuits; amplitude (0–80 mA in 500 Ω); waveform (asymmetric biphasic); type (direct current); pulse frequency (50 Hz); pulse duration (50 μs); pulse pattern (continuous); and electrodes (self-adhesive 50 mm x 50 mm).

Each subject performed the first TENS session with the clinician in the clinic, in order to set the pulse frequency and pulse duration, and to learn how and where to place the electrodes. A pair of electrodes was placed on the trapezium between the acromion and the C7 vertebra. The remaining pair was placed on the long axis of the muscular belly of the masseter, on the line between the gonial angle and the canthus, 1 cm above the gonial angle. At home, patients performed a continuous 60-minute daily TENS session for 10 weeks. At the end of the intervention period, all primary and secondary outcomes (THI, VAS, ROM, CTS, PTS, audiometry, tinnitometry) were assessed again, and compared with pre-therapy values. Primary and secondary outcomes were presented as descriptive statistics, and compared before and after therapy.

RESULTS

A total of 15 patients (12 females and 3 males, mean age 53.2±18.19 years) with persistent tinnitus of constant intensity was selected. Three patients refused to be included in the study, and 3 patients were unable to complete the treatment cycle (one due to financial reasons, two due to a missed follow-up appointment). Thus, a total of 9 patients (7 women and 2 men, mean age 55.3±16.89 years) were included in the analysis. In terms of tinnitus onset, 8 patients had experienced symptoms for more than 1 year, and a single patient had symptoms for over 8 months. A range of sound types [pure tone, 7 patients; noise (comprised of multiple sounds), 2 patients] and descriptions [whistle, 5 patients; sizzle, 3 patients; hiss (like a gas leak), 1 patient] were documented. Seven patients reported that their tinnitus was more often perceived at night.

At the 10-week follow-up, the mandibular ROM had improved in all patients. Increases were observed for average active jaw opening (from 43.2±6.6 mm to 45.9±7 mm), passive jaw opening (from 47.7±6.9 mm to 49.5±8.7 mm), protrusion (from 7.2±1 mm to 8.1±1.8 mm), right laterotrusion (from 11.3±2.4 mm to 12.3±3.3 mm), and left laterotrusion (from 10.1±3.6 mm to 11±2.4 mm). PTS and CTS values were lower after therapy (PTS, 18±0.86; CTS, 1.24±0.89) compared to baseline (PTS, 1.86±1; CTS, 2.07±1.05).

In terms of cervicofacial muscle pain, decreases in scores at the end of therapy were observed for average muscular pain (from 5.43±1.98 to 2.81±1.91, percentage decrease of 48.26%), maximum muscle pain (from 6.67±2.05 to 3.67±2.49, percentage

Table I. *Tinnitometric data (expressed in dB) obtained before and after 10 weeks of transcutaneous electrical nerve stimulation therapy.*

	Hearing threshold	Tinnitus intensity
SUBJECT	BEFORE	AFTER
1	52	51
2	25	54
3	76	72
4	20	20

decrease of 45%), and muscle pain at the time of the assessment (from 4.18±3.16 to 2.7±2.36, percentage decrease of 35.37%) (Fig. 3A). In terms of perceived tinnitus intensity, scores were decreased at the end of therapy for perceived volume of tinnitus (from 6.1±1.36 to 5±1, average percentage decrease of 18.18%), level of anxiety connected to tinnitus (from 6.3±1 to 6.1±2.20, percentage decrease of 3.17%), and tolerability of tinnitus (from 6.3±1.14 to 6±1.80, percentage decrease of 5.26%). In terms of the influence of tinnitus on mood, scores after therapy (5.2±1.99) were higher than before therapy (4.4±2.07, an increase of 18.18%) (Fig. 3 B,C).

Improvements in quality of life were observed. The mean pre-therapy THI score of 31.1 was higher than the mean post-therapy score of 23.8, yielding a mean difference of 7.3 points. Six patients had improvements of at least 6 points, reflecting significant improvements following treatment (Fig 3D). Tinnitometric data are shown in Table I. The mean reduction in level of sensation values after therapy was 4.44 Db, which equated to a percentage reduction of 44.4%.

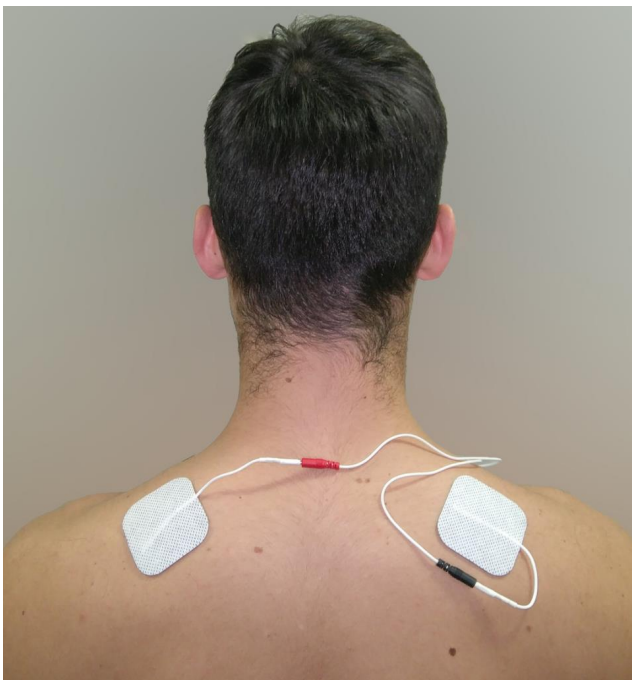

Fig. 2. *Electrode placement on the trapezium between the acromion and the C7 vertebra.*

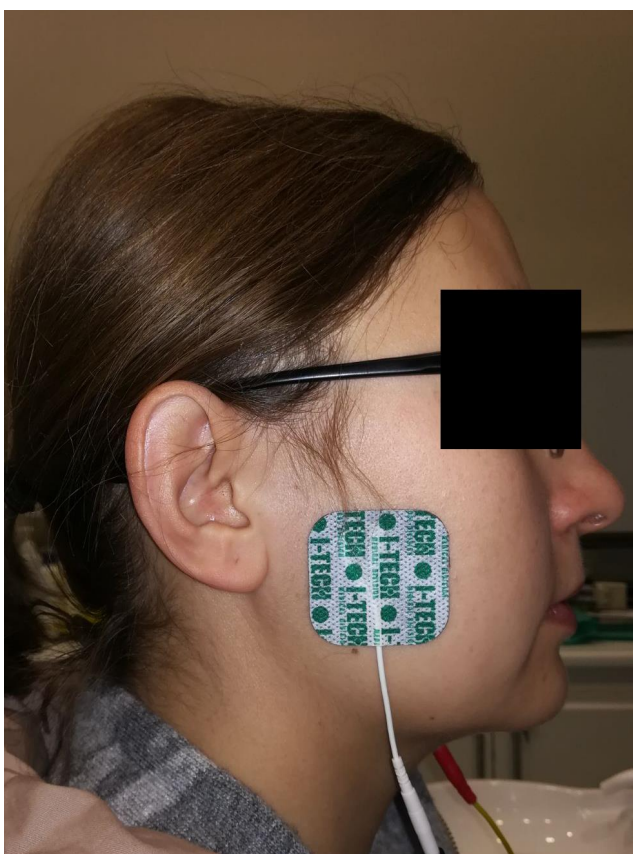

Fig. 1. *Electrode placement on the long axis of the muscular belly of the masseter, on the line between the gonial angle and the canthus, 1 cm above the gonial angle.*

DISCUSSION

The purpose of this study was to evaluate whether TENS therapy could be beneficial to patients complaining of somatic tinnitus. Comparing the results of the present study with previously published data is difficult, as each study has used different sample selection protocols and assessment methods. Many authors have highlighted the need for placebo-controlled studies to evaluate the placebo effect in treatment protocols for tinnitus (9, 10). The perceived intensity of tinnitus changed from a mean score of 6.1 to 5 (percentage reduction of 18.18%). A reduction of this value occurred in 66.67% of the patients evaluated. This result is in agreement with the study by Bonaconsa et al. (11) which reported a reduction of 1.45 points among 53% of patients. The article by Lee et al. (12)

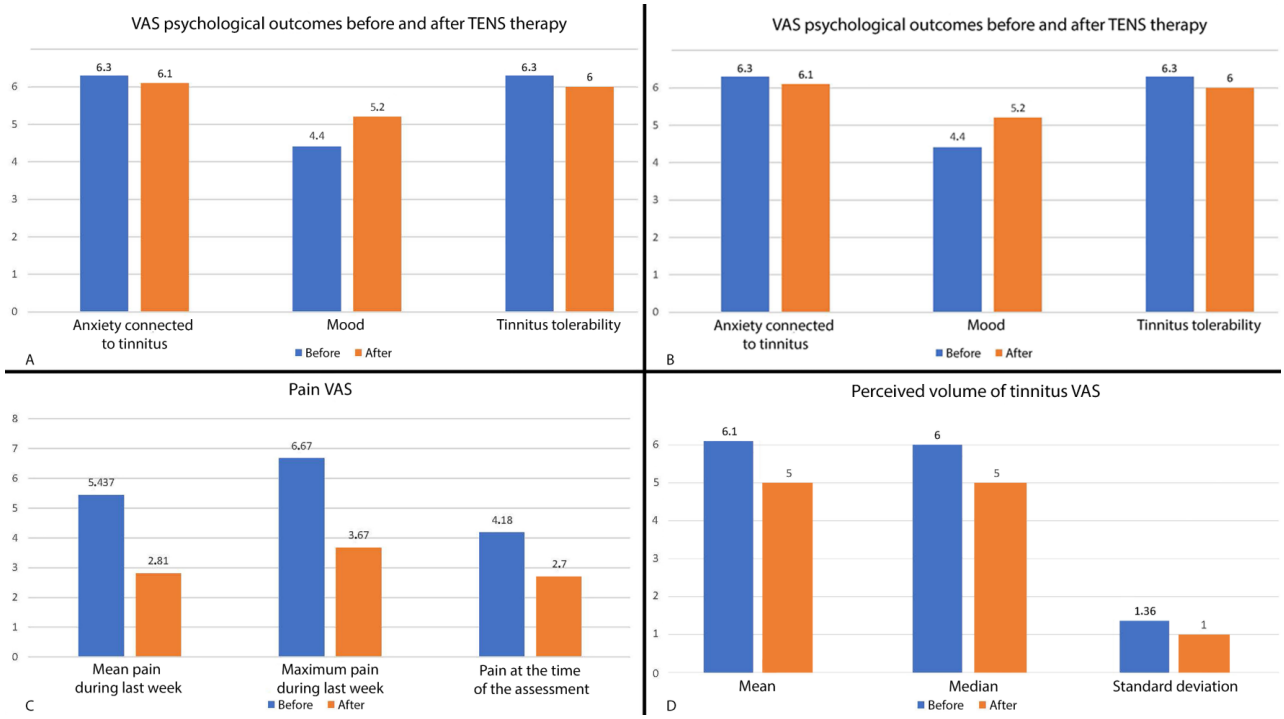

Fig.3. ***A)*** *Cervicofacial muscle pain assessed with a visual analogue scale (VAS, 0 – 10 scale), before and after 10 weeks of transcutaneous electrical nerve stimulation therapy.* ***B)*** *Perceived volume of tinnitus, as assessed with a visual analogue scale (VAS, 0 – 10 scale), before (SD = 1.36) and after 10 weeks of transcutaneous electrical nerve stimulation therapy (SD = 1.00).* ***C)*** *Visual analogue scale scores (VAS, 0 – 10 scale) for level of anxiety connected to tinnitus, tinnitus influence on mood, and tolerability of tinnitus, before and after 10 weeks of transcutaneous electrical nerve stimulation therapy.* ***D)*** *Tinnitus Handicap Inventory (THI) questionnaire scores before (SD = 11.5) and after 10 weeks of transcutaneous electrical nerve stimulation therapy (TENS) (SD = 12.3).*

provided similar data, identifying a mean reduction of 0.9 points in perceived intensity. On the other hand, Herraiz (2007) found an improvement in 46% of the participants performing TENS for two weeks at home. That study, however, did not distinguish between somatosensory tinnitus, and tinnitus associated with otolaryngologic pathology. All patients had significant tinnitometric improvements (mean decrease was from 10 dB to 5.6 dB, 44.44% reduction). Nevertheless, comparisons with existing literature could not be made, as no studies have used a similar research protocol to assess this outcome.

It is interesting to consider that a significant reduction in tinnitus intensity, as assessed with tinnitometry, does not imply a similar improvement in VAS assessments tailored to assess self-perception of tinnitus intensity, or quality of life as assessed by THI (10, 14). Confirmation of the efficacy of this therapeutic protocol would require a larger sample size, as well as an extension of the follow-up period to evaluate whether the reduction in intensity of tinnitus that appears after 10 weeks corresponds to a progressive improvement in patients' quality of life.

It is important to investigate possible occult pathologies that may not have a dental cause. For this reason, it would be appropriate to approach the treatment of a patient with tinnitus with an interdisciplinary team specialized in the various aspects of diagnosis and therapy (otolaryngologists, neurologists, psychiatrists and psychologists). A lack of knowledge in somatosensory tinnitus etiology leaves little option but to consider and use all possible therapies validated by the literature to find one that, for a specific patient, is effective, at least in part. Clinicians must have the ability to make a differential diagnosis between different types of tinnitus in order to successfully manage these patients, or refer the patient to the appropriate specialist.

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