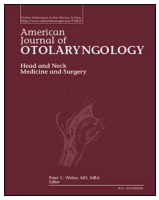
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Transcutaneous Electric Nerve Stimulation in Chronic Subjective Tinnitus

Zehra Aydoğan [a], Merve Cinar Satekin [b], Muhammed Sefa Uyar [c], Songül Aksoy [d], Suna Tokgoz-Yilmaz [a,b,*,1]

[a] Department of Audiology, Faculty of Health Sciences, Ankara University, Ankara, Turkey
[b] Ankara University, Faculty of Medicine, Otolaryngology Department, Audiology, Speech, Balance Disorders Diagnosis and Rehabilitation Unit, Ankara, Turkey
[c] Ankara University, Faculty of Medicine, Otolaryngology Department, Ankara, Turkey
[d] Department of Audiology, Faculty of Health Sciences, Lokman Hekim University, Ankara, Turkey

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ABSTRACT

Objective: It is aimed to determine the therapeutic role of transcutaneous electrical nerve stimulation (TENS) on chronic subjective tinnitus with a randomized and comparative analysis.
Method: 46 individuals with normal hearing, chronic subjective tinnitus, aged 20–65; randomly divided into the study (TENS therapy) and tje control groups. The control group ($n = 23$) was informed only about tinnitus, while the study group ($n = 23$) received TENS therapy (20 sessions in 4 weeks). Before TENS therapy, tinnitus-related evaluations of all participants [tinnitus frequency, loudness, minimum masking level (MMS), residual inhibition (RI)] were made and Tinnitus Handicap Inventory (THI), Visual Analogue Scale (VAS), Short Form 36 (SF-36), and The Quality of Life Scale were applied to the participants. These evaluations and questionnaires were repeated after 4 weeks of the therapy.
Results: There was a significant decrease in the tinnitus severity after TENS therapy in the study group ($p = 0.003$). Moreover, it was found that VAS (loudness and annoyance), THI (functional, emotional and total score), SF-36 (physical function, physical role, pain, general health, vitality, emotional role and social function) values improved compared to before TENS therapy and the difference was significant ($p < 0.05$). There was no significant difference between the first and last evaluations of the control group ($p > 0.05$).
Conclusion: TENS is an effective, practical and reliable therapy method in reducing severity, loudness, and annoyance of tinnitus, and increasing the quality of life in individuals with chronic subjective tinnitus.

1. Introduction

Tinnitus is one of the issues which are most interested in otology in recent years. It is defined as the sound heard in the ear or the conscious perception of a sound originating from the head without any external stimulus [1,2]. It is evaluated in two main categories as objective and subjective [3]. Subjective tinnitus is defined as the perception of irregular sound at different frequencies without any external stimulus, and according to studies conducted on large populations in recent years, it is seen in approximately 17 % of the general population [2]. Many studies suggest that tinnitus may be accompanied by psychological disorders such as anxiety, depression, irritability, and/or possible physiological problems in the head, neck, and mandible [4,5]. In the majority of patients, these symptoms may be the result of tinnitus and/or increased environmental stress and awareness of tinnitus may also result in increased tinnitus [5]. In 1–3 % of the general population, the loudness of tinnitus is so high that it affects the quality of life [3]. How much tinnitus affects a person's life depends on its severity, frequency, and importance. Anxiety caused by tinnitus is also a factor that increases sensitivity in the development of chronic diseases that reduce the quality of life [6].

Although it has been studied for many years and new developments in medicine, a common conclusion has not been reached on the pathophysiology of tinnitus. Due to the lack of information about the occurrence and persistence of tinnitus, treatment strategies have also been symptomatic and often inadequate [7]. Until now, different methods have been applied in the treatment of tinnitus such as medical and surgical treatments, masking treatment, psychotherapy and electrotherapy, but no definite and clear success has been achieved [8]. Tinnitus treatment is determined according to the specific causes and

* Corresponding author at: Ankara University Health Sciences Faculty, 06100 Ankara, Turkey.
E-mail addresses: sunatokgoz@yahoo.com, sunayilmaz11@gmail.com (S. Tokgoz-Yilmaz).
[1] Suna Tokgoz-Yilmaz takes responsibility for the integrity of the content of the paper at all stages of refereeing and publication, also post-publication.

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location of tinnitus. The main purpose of treatment is to eliminate tinnitus completely if possible, but when not possible, to try to minimize the discomfort caused by tinnitus. The majority of those who applied to the Otorhinolaryngology Department due to tinnitus consist of patients with chronic (at least 6 months) subjective tinnitus. The recommendation usually given to these patients is to get used to living with tinnitus. Instead of trying to get used to this situation, it may be possible to improve the quality of life of the individuals with chronic subjective tinnitus with an appropriate therapy method.

Electrical stimulation, which dates back to the 1800s, can be done in the treatment of otological diseases by giving stimulus to the mastoid, post-auricular skin, eardrum, promontorium, round window, and scala media [9]. It is reported that the applied current decreases or inhibits the spontaneous discharge rate by creating hyperpolarization in the nerve fibers [10,11]. Electrical stimulation can be applied by introducing anodic or cathodic currents. It has been stated that better results are obtained with anodic current [12].

Transcutaneous Electrical Nerve Stimulation (TENS), an electrotherapy method used in the treatment of acute and chronic pain, was first developed in the early 1970s as a scanning technique for satisfactory pain with the implantation of an electrical stimulator [13]. With the TENS method, electrical stimulation is applied along the intact surface of the skin, resulting in reflex activation of sympathetic inhibitory neurons and reflex inhibition of parasympathetic excitatory neurons in the area of the pathology. Electrical features of TENS such as stimulation frequency and intensity, pulse duration and cycle can be selectively determined to activate different neuron fibers [13].

In recent years, TENS has been used as an effective method in the therapy of tinnitus. Unlike traditional electrical stimulators, TENS uses more sensors for stimulation. Because pain and tinnitus are subjective, maskable, and changeable over time, they are considered to be similar conditions. It is thought that TENS therapy reduces the existing spontaneous nerve discharge as a result of hyperpolarization in the peripheral neural network of the 8th nerve (at lower basilar membrane levels of the cochlea) with positive current, and thus tinnitus regresses. Prevention of abnormal messages originating from the cochlea that cause tinnitus by increasing cochlear functions and blood flow after direct electrical stimulation of the cochlea is a possible mechanism of TENS therapy [14]. Although rates fluctuate depending on experimental design, TENS efficacy has been reported up to 80 % [11]. It has been reported that TENS provides long-term relaxation in one third of patients with tinnitus [15]. TENS is a non-invasive and easy-to-apply method, but it has limitations as the underlying mechanisms in tinnitus remain unclear and treatment efficacy is not consistent [14].

In this study, it is primarily aimed to investigate the effects of TENS method on tinnitus loudness and quality of life in individuals with normal hearing and chronic subjective tinnitus. In addition, tinnitus is an important public health problem that is frequently seen in the society, reduces the quality of life, and causes financial and psychological losses. Determining the effectiveness of TENS therapy will giving suggestions that can make a difference in the quality of life of the individuals with tinnitus, contribute to multidisciplinary studies, and also it can give direction to the clinicians' approaches.

2. Materials and methods

This study involved data collected between March 2020 and December 2021 at Audiology Unit of ENT Department, Faculty of Medicine, Ankara University. Informed consent was given by all participants before the study, and the Declaration of Helsinki principles were followed (Human Research Ethics Committee, Faculty of Medicine, Ankara University, no: İ2-73-20).

2.1. Participants

A total of 46 individuals (28 females and 18 males) aged 20–65 years were included in the study, who applied to ENT department with tinnitus complaint. Subjects with subjective tinnitus, who had tinnitus for at least 6 months, and who had not received any tinnitus treatment in the last year, were included as a result of tinnitus evaluation. Individuals were randomly divided into two groups as control and study (TENS) groups.

The inclusion criteria were normal otoscopic findings; normal hearing (pure tone hearing thresholds <20 dB at 0.5, 1, 2 and 4 kHz and an air–bone gap <10 dB HL); normal tympanogram (with a type A); normal limits of ipsilateral and contralateral acoustic reflex thresholds (at 0.5, 1, 2 and 4 kHz); and no systemic diseases. For both groups, the criteria for selecting participants were that the pain score, which is a sub-parameter of the SF 36 scale, was at least 45 and that the patients had subjective neck pain complaints.

The exclusion criteria were abnormal hearing and immittance-metric measurements; hypertension, hyperlipidaemia or diabetes; any middle-ear pathology such as otosclerosis or otitis media; being diagnosed with acoustic neuroma (monitored or treated); previous ear surgery and/or cranial surgery; Meniere's disease or active ear discharge; and any neuropsychiatric disease. Since the use of a pacemaker is contraindicated for TENS, individuals with pacemakers were also excluded from the study.

2.2. Procedure

Pure tone test and psychoacoustic assessment of tinnitus were performed with AC-40 clinical audiometer (Interacoustics, Denmark). Tinnitus psychoacoustic assessment includes measures of tinnitus severity (dB), frequency (Hz), minimum masking level (MMS), and residual inhibition (RI). Visual Analogue Scale (VAS) and Tinnitus Handicap Inventory (THI) were also used to measure tinnitus loudness. Short Form 36 (SF-36) Quality of Life Scale was used to measure the effect of tinnitus on quality of life. VAS, THI and SF-36 assessments consist of behavioral tests including paper-pencil tests.

2.2.1. Tinnitus evaluation form (demografic informations for tinnitus)

The form has been prepared by the authors for information purposes. The form consists of 17 questions about information such as age, gender, education level, smoking/alcohol use, onset time of tinnitus, duration, type of tinnitus, therapy method for tinnitus, hearing loss, feeling of hum and fullness in the ear, hyperacusis, presence of balance problem. The forms were filled by asking participants verbally.

2.2.2. Visual analogue scale (VAS)

The patients were asked to mark the severity of the resonance and the level of disturbance from the resonance on two separate measurement lines, each 10 cm long. The marked point was measured using a ruler. Greater deviance from zero indicates higher resonance intensity (loudness) and increased disturbance (annoyance).

2.2.3. Tinnitus handicap inventory (THI)

THI, one of the most used questionnaires to determine the severity and level of tinnitus, has high reliability in test repetitions [5]. THI is unaffected by age, gender and hearing loss, gives clear results, can be applied easily and gives more specific measurements psychometrically. The questionnaire consisted of 25 questions is answered with 'yes' (4 points), 'sometimes' (2 points) or 'no' (0 points). The total THI score is range from 0 to 100 and a higher THI score indicates a greater tinnitus-related handicap. THI has subdomains such as emotional, functional and catastrophic, and the tinnitus level is determined according to the THI total score (level 1–5). We used Turkish validity and reliability of THI [16].

2.2.4. Short form 36 (SF-36) quality of life scale

It was used to examine the health status and quality of life of individuals. This scale includes 36 items and evaluates 8 subdomains

(physical function, limitation-physical role, limitation-emotional role, pain, vitality, social function, mental health, general health perception). The score of each subdomains in the scale ranges from 0 to 100. The higher the score of each subdomains, the higher the health-related quality of life is scored [17].

2.2.5. TENS therapy

After the evaluation process, 20 sessions (5 sessions per week, 4 weeks) of TENS were applied to the patients who were indicated. The conventional type of TENS device (Fig. 1) is including current of 50–100 Hz (frequency), 40–70 mA (wavelenghts), 10–30 V amplitude. 2 or 4 electrodes consisting of carbon silicon compound are used in TENS therapy. These variables are suitable mode for tinnitus. The TENS protocol we used was as follows; the amplitude was between 25 and 66 miliamperes (mA) with 50 Hertz (Hz), 10 Volt (V) and the pulse duration was between 50 and 100 microseconds (μs). In the our TENS protocol, there was 4 electrodes (Fig. 2). TENS applied without any complications to the patients, with a duration of 30 min per session. Evaluations and paper-pencil tests (VAS, THI, SF-36) applied to the study group before and after the TENS therapy. All evaluations were repeated 4 weeks after the first evaluation for the control group. The effectiveness of TENS treatment on chronic subjective tinnitus was determined primarily by comparing the findings of the study group before and after TENS treatment, and comparing the results between the groups.

2.3. Statistical analysis

Statistical analysis was performed using the SPSS version 21.0 software (IBM Corp.; Armonk, NY, USA). The sample size was determined using the G*Power version 3.1 software (with the parameters: correlation of interest ρH1 = 0.5, α error rate = 0.05, power = 0.95). Percentage values for categorical variables were was used for the descriptive statistics. The mean ± standard deviation values were used in the descriptive statistics of age and tinnitus duration variables. The values of VAS (tinnitus loudness and annoyance), THI and SF-36 were assessed and before and after TENS therapy values were compared. Whether the data fit the normal distribution was evaluated with histogram curves and bell curves. When comparing before and after therapy, a paired samples *t*-test was used to compare normally distributed data. After evaluating and calculating the numerical difference before and after therapy, Student's t-test or Mann Whitney-*U* test was used for two-group comparisons. A *p*-value of 0.05 was considered statistically significant.



Fig. 1. TENS device and 4 electrodes.



Fig. 2. TENS therapy with 4 electrodes.

3. Results

The mean age (and standard deviation values) of the 46 individuals who participated in the study are shown in Table 1. There was a significant difference between before and after TENS therapy for tinnitus severity ($p = 0.003$), VAS-tinnitus loudness ($p = 0.001$), VAS-annoyance ($p = 0.001$), THI-functional ($p = 0.05$), THI-emotional ($p = 0.005$), THI-total score ($p = 0.01$) in TENS group (Table 2) (Figs. 3, 4).

A significant difference was found between before and after TENS therapy for all sub-parameters of SF-36, except mental health ($p < 0.05$) (Table 3) (Fig. 5).

In the control group, there was no statistically significant difference between the first and last evaluation in tinnitus severity, VAS-tinnitus loudness, VAS-annoyance and all sub-parameters of THI and SF-36 ($p > 0.05$) (Table 2) (Figs. 3, 4, 5). There was a significant difference for VAS-tinnitus loudness ($p = 0.005$), VAS-annoyance ($p = 0.047$) and only

Table 1
Participants' demographic characteristics ($N = 46$).

	Control group Mean ± SD	TENS group Mean ± SD	*p* value
Age (year)	40.08 ± 11.76	38.58 ± 8.97	0.43
Gender, n (%)			
Female	13 (56.5 %)	15 (65.2 %)	0.69
Male	10 (43.4 %)	8 (34.7 %)	0.58

SD: Standard Deviation; Chisquare test; $p > 0.05$.

Table 2
Comparison of tinnitus severity, VAS and THI scores before and after TENS therapy.

	TENS group Mean ± SD			Control group Mean ± SD			Intergroup Mean ± SD		
	First evaluation	Last evaluation	*p* value	First evaluation	Last evaluation	*p* value	TENS group	Control group	*p* value
Tinnitus severity (dB)	54.86 ± 13.44	42.60 ± 18.16	0.003*	55.08 ± 14.26	55.26 ± 14.16	0.4	−9.04 ± 2.08	−7.24 ± 2.78	0.138
VAS-Tinnitus loudness	6.34 ± 1.89	3.34 ± 2.36	0.001*	6.04 ± 2.09	6.00 ± 1.4	0.8	2.57 ± 1.03	1.27 ± 1.46	0.005**
VAS-Annoyance	6.30 ± 1.86	3.21 ± 2.25	0.001*	5.95 ± 1.32	5.64 ± 1.44	0.07	2.70 ± 1.75	1.53 ± 1.96	0.047**
THI-Functional	19.56 ± 12.29	14.13 ± 10.63	0.05*	22.17 ± 3.24	21.07 ± 4.06	0.5	−7.08 ± 5.48	−10.17 ± 9.8	0.12
THI-Emotional	14.45 ± 6.26	5.27 ± 4.67	0.005*	17.5 ± 7.30	16.05 ± 5.38	0.2	−8.23 ± 7.61	−4.98 ± 5.96	0.4
THI-Catastrophic	4.06 ± 5.69	3.02 ± 3.81	0.06	10.8 ± 5.12	10.64 ± 5.34	0.9	−2.58 ± 4.30	−2.9 ± 3.18	0.87
THI-Total score	38.78 ± 23.50	22.69 ± 18.83	0.001*	50.15 ± 13.45	48.35 ± 23.79	0.6	−15.41 ± 12.40	−12.3 ± 15.17	0.03**

TENS: Transcutaneous Electric Nerve Stimulation; VAS: Visual Analog Scale; THI: Tinnitus Handicap Inventory; Paired Samples t-test (*p < 0.05); Mann Whitney *U* test (**p < 0.05).

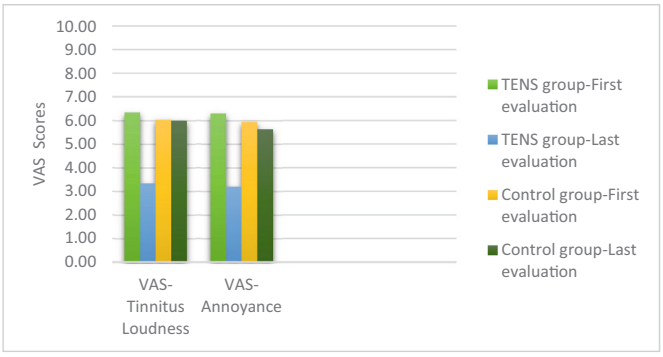


Fig. 3. VAS scores before and after TENS therapy.
TENS: Transcutaneous Electric Nerve Stimulation, VAS: Visual Analog Scale.

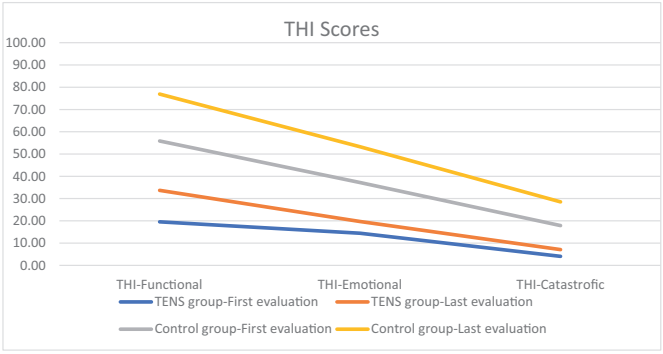


Fig. 4. THI scores before and after TENS therapy.
TENS: Transcutaneous Electric Nerve Stimulation, THI: Tinnitus Handicap Inventory.

total score of THI ($p = 0.03$) in the first and last evaluation between intergroup (Table 2). There was no significant difference for all sub-parameters of SF-36 in the first and last evaluation between intergroup (p > 0.05) (Table 3).

4. Discussion

TENS, effective in the treatment of pain, has been used as an alternative method for tinnitus for many years. TENS protocol is used for treatment in pain, inflammation, edema, ligament dysfunctions and spinal diseases since the 1800s. It is assumed that TENS modulates tinnitus symptoms by increasing cochlear blood flow or capturing abnormal sensory signals, which is based on gate control theory [14,18]. It has also been reported that TENS reduces pain by activating neural plasticity, and provides suppression in tinnitus through somatosensory-auditory interactions at the level cochlear nucleus and inferior colliculus [19]. An animal study showed that electrical stimulation applied to the round window can reduce the spontaneous peripheral neural firing that occurs after cochlear injury [20]. We hypothesized that TENS is an effective and attractive alternative method for the therapy of tinnitus based on the aforementioned mechanisms.

Tinnitus can negatively affect the quality of life of patients [21,22]. A study by Salazar et al. showed that the prevalence of depression in patients with tinnitus was 33 %, emphasizing the importance of assessing the quality of life in individuals with tinnitus [23]. THI is a tinnitus-specific tool designed to assess the impact of tinnitus on daily life [24]. It provides valuable insight by determining the effect of tinnitus on life according to patient perception with total score that include three sub-parameters (functional, emotional and catastrophic) [24].

In a study, the effectiveness of TENS in chronic tinnitus was examined with THI and it was observed the decrease in THI scores after TENS therapy (Lee et al., 2014). In another study investigating the effect of TENS in chronic subjective tinnitus, it was reported that the post-therapy THI scores decreased significantly in TENS group (20 participants) compared to the placebo group (20 participants) [6]. Similar to

Table 3
Comparison of SF-36 scores before and after TENS therapy.

SF-36 Scale	TENS group Mean ± SD			Control group Mean ± SD			Intergroup Mean ± SD		
	First evaluation	Last evaluation	*p* value	First evaluation	Last evaluation	*p* value	TENS group	Control group	*p* value
PF	84.56 ± 18.83	88.04 ± 14.59	0.008	78.69 ± 26.11	72.17 ± 21.28	0.834	6.17 ± 7.60	4.11 ± 23.46	0.05
RP	63.04 ± 41.19	73.90 ± 27.67	0.030	76.08 ± 36.52	72.17 ± 30.51	0.829	19.11 ± 28.68	1.47 ± 3.99	0.065
BP	49.56 ± 18.44	55.73 ± 16.04	0.003	69.26 ± 27.20	72.05 ± 24.20	0.291	9.76 ± 11.85	5.05 ± 15.02	0.05
GH	64.65 ± 18.44	69.30 ± 16.26	0.002	59.34 ± 16.54	63.62 ± 23.4	0.232	40.35 ± 134.09	3.64 ± 14.25	0.199
VT	49.78 ± 16.05	53.91 ± 14.45	0.015	56.08 ± 26.20	55.08 ± 26.84	0.769	24.41 ± 8.31	1.17 ± 17.27	0.855
SF	58.26 ± 23.22	61.17 ± 22.78	0.05	79.89 ± 23.58	77.12 ± 64.55	0.567	0.55 ± 1.50	2.20 ± 20,83	0.91
RE	69.56 ± 36.12	79.70 ± 31.37	0.047	65.70 ± 41.62	76.81 ± 29.11	0.057	11.52 ± 26.50	9.81 ± 30.66	0.686
MH	56.34 ± 15.62	57.73 ± 14.31	0.08	54.26 ± 20.91	57.39 ± 21.52	0.413	6.08 ± 4.60	4.11 ± 23.46	0.50

TENS: Transcutaneous Electric Nerve Stimulation; SF-36:Short Form-36 Health Survey; PF: Physical functioning; RP: Role physical; BP: Bodily pain; GH: General health perception; VT: Vitality; SF: Social functioning; RE: Role emotional; MH: Mental health; Paired Samples *t*-test; $p < 0.05$.

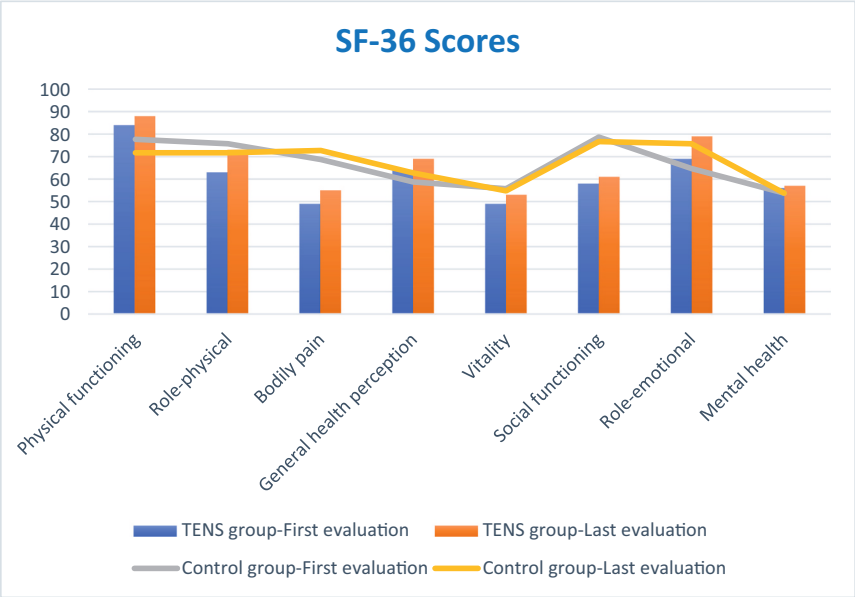


Fig. 5. SF-36 scores before and after TENS therapy.
SF-36: Short Form 36 Health Survey.

these findings, we found significant improvement in the functional ($p = 0.05$), emotional ($p = 0.005$) and total scores ($p = 0.001$) of THI after TENS therapy in the TENS group according to the control group. A significiant difference was found in the total score of THI in the first and last evaluation between intergroup ($p = 0.03$). In addition, there was a positive correlation ($r > 0.5$) between VAS-tinnitus loudness and tinnitus severity (dB) of participants after TENS therapy. However, VAS-tinnitus loudness and VAS-annoyance degree are also related to the degree which patients are affected by their tinnitus-related symptoms [25].

In a meta-analysis study, it was showed that TENS therapy resulted in significant improvements in both THI and VAS scores, with an overall mean reduction of 7.55 (out of 100) for THI and 0.65 for VAS (out of 10). Although tinnitus symptoms do not completely disappear in these patients, it has been reported that the perception of distress caused by the symptoms of the patients seems to decrease with TENS therapy [18]. In another study, the change in tinnitus loudness was evaluated according to VAS, and it was reported that VAS decreased significantly after TENS therapy (from 6.47 to 6.0, $p < 0.01$) [15]. In another study, it was reported that 53 % of patients with tinnitus decreased in VAS scores after electrical stimulation [14]. Our study is similar and consistent with the literature. We questioned VAS-tinnitus loudness and VAS-annoyance degree of the study group before and after TENS therapy. We found a significant decrease (in other words, the improvement) of VAS scores in the TENS group.

In a study, 22 patients were evaluated the effectiveness of TENS using VAS, THI, Nottingham Health Profile and SF-36. A significant difference was found after TENS therapy in all sub-parameters of SF-36. They emphasized that TENS therapy increases the quality of life in individuals with tinnitus and is an effective method in tinnitus [26]. TENS was applied to 23 patients 3 sessions a week for 4 weeks, SF-12 physical and SF-12 mental questionnaires were used to evaluate the quality of life in another study [27]. They were reported a significant improvement after TENS therapy compared to before. In our study, we applied TENS therapy to the study group ($n = 23$) and we found statistically significant improvement in all sub-parameters of SF-36, except mental health, before and after TENS therapy in the study group. These findings were similar and consistent with the literature.

It has been reported that there is a significant relationship between the quality of life and both audiological and psychological variables in individuals with tinnitus, and that the quality of life decreases as the these variables decrease [28]. Similar to the literature, we found significant differences in tinnitus severity, which is defined as the audiological parameter and variable of tinnitus, as well as VAS and SF-36 scores in our study.

We analyzed several variables between the TENS group and the control group and demonstrated that there was a significant difference between the two groups. In the light of our findings, we observed that TENS therapy reduced tinnitus severity, loudness and annoyance degree of tinnitus in individuals with subjective tinnitus. TENS can eliminate the risks associated with invasive procedures. We concluded that TENS therapy, as a non-invasive method, is an approach that improves the coping skills and quality of life of individuals with chronic subjective tinnitus.

5. Conclusion

In summary, tinnitus is an important public health problem that is frequently seen in the society. In this study, we determined the effectiveness of TENS therapy on tinnitus, which reduces the quality of life and can cause financial and psychological losses. TENS is an effective, practical and reliable therapy method in reducing tinnitus severity, loudness, annoyance and increasing the quality of life in individuals with chronic subjective tinnitus.

CRediT authorship contribution statement

Zehra Aydoğan: Conceptualization, Writing and draft preparation, Data Collecting. Merve Cinar Satekin: Conceptualization, Writing and draft preparation, Methodology, Data Collecting. Muhammed Sefa Uyar: Writing and draft preparation, Suna Tokgoz-Yilmaz: Conceptualization, Writing and draft preparation, Reviewing and Editing, Methodology.

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Declaration of competing interest

None.

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