STUDY PROTOCOL (20.12.2021)

Title of Study:

Evaluation of the Effect of Muscle Activity on Subjective Tinnitus in Temporomandibular Disorders

Title, name, area of expertise and place of duty of principal investigator:

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Where the research will be conducted:

Kütahya University of Health Sciences Faculty of Dentistry

PHASE OF THE RESEARCH AND TYPE	PHASE 1	☐
	PHASE 2	☐
	PHASE 3	☐
	PHASE 4	☐
	observational drug study	☐
	Medical device clinical research	☐
	Performance evaluation studies with in vitro medical diagnostic devices	☐
	Non-drug clinical research	☒
	If other, specify:	

The planned date range of the research: 25.12.2021-15.11.2022

The hypothesis of the research:
$\mu = 1$ hypothesis: Temporomandibular disorder accompanied by subjective tinnitus and treatment of bruxism with an occlusal splint; It has an effect on the decrease in the levels of tinnitus, bruxism and temporomandibular disorder.

$\mu = 0$ hypothesis: Temporomandibular disorder accompanied by subjective tinnitus and treatment of bruxism with occlusal splint; It has no effect on the decrease in the levels of tinnitus, bruxism and temporomandibular disorder.

Introduction-Purpose Section:

Temporomandibular disorders; is a general term describing disorders of the masticatory muscles, temporomandibular ligaments, and temporomandibular joint (TMJ). The most common symptoms of these disorders are pain in the preauricular region and masticatory muscles, limitation/irregularity in joint movements and sounds coming from the joint. Additional symptoms include; headache, tinnitus, dizziness, hearing loss, sleep disturbance, and chronic fatigue. Bruxism is one of the most common predisposing factors that cause temporomandibular disorders.

Bruxism is a repetitive jaw-muscle activity that occurs with mandible movement characterized by clenching and/or grinding of the teeth. Bruxism can occur during the day or night while sleeping or awake. While clenching is more prominent in diurnal bruxism, grinding is seen in addition to clenching in nocturnal bruxism. Factors such as stress, occlusal irregularities, allergies, and sleep quality are discussed in its etiology. Treatment includes botulinum toxin injection and/or occlusal splint.

Occlusal splints are one of the most common and first-choice treatment modalities in patients with TMD and bruxism, as they are a non-invasive and easily accessible treatment option. These splints are used to correct the static and dynamic effects of the stomatognathic system. With the occlusal splint, equal and balanced occlusal contact is achieved without permanently changing the resting position of the mandible and/or dental occlusion. It is usually in the form of a dental retainer or removable prosthesis made of hard acrylic. The most commonly used type of occlusal splint is the Michigan type bite splint. This splint is mostly used in the maxilla. The main purpose of this appliance is to separate the occlusion, put the condyle in a centric position, relax the chewing muscles and prevent further tooth wear due to parafunctional activity. The main feature of the Michigan type bite splint is that it can easily provide centric and canine-protected occlusion.

Tinnitus is defined as the perception of sounds in one's ears or inside the head without any acoustic stimulus. Sounds can be perceived in the ear or in the head. Microtrauma associated with repetitive activities, such as bruxism, is considered a risk factor for the onset and persistence of muscle pain and may be directly related to the symptom of tinnitus. Hyperactivity in the masticatory muscles as a result of bruxism may affect the tensor tympani muscle and the auditory system and trigger tinnitus. [1] Ramirez et al. reported that the tensor veli palatini muscle

lost its function in patients with bruxism, and the position of the tympanic membrane and malleus could change due to its union with the tensor tympani muscle. [2] Therefore, they reported that velopharyngeal, neck and facial movements have an important role in the symptoms of otic-temporomandibular disorder. [2] In the study by Camparis et al., it was found that the frequency of tinnitus is high in patients with sleep bruxism and chronic myofascial pain; At the same time, it was reported that the number of painful areas on palpation in the chewing and cervical muscles and the absence of teeth were more common in the tinnitus group, and the tinnitus frequency was higher in patients with sleep bruxism. [3] In the study of Kuttila et al., it was reported that the pain in the chewing muscles in patients with tinnitus was higher than the control group. [4] Bernhardt et al. reported that tinnitus patients had more muscle and TMJ pain than the control group. [5] According to the positive correlation between bruxism and tinnitus; Since oral parafunctions trigger both conscious and unconscious jaw movements, it is thought that abnormal activity of the masticatory muscles and jaw joint may trigger a more intense tinnitus sensation.

Electromyography (EMG is the most reliable method to record muscle function and activity with electrical potentials. It is a graphical recording of the electrical potentials of the muscles. In the EMG method, the tool is the electrode that provides the connection between the biological tissue and the recording system. There are 2 basic types of electrodes. These are superficial and needle electrodes. Surface electrodes are noninvasive. They do not cause infection. With this technique, only the activities of localized muscles close to the skin can be detected. Therefore, masseter or anterior temporal muscle activities are mostly examined. Patients do not want this application because the hair must be cut to detect the medial and posterior fibers of the temporal muscle. If the activity of the pterygoid muscle is detected anatomically difficult. Low reproducibility as a result of impedance inconsistency. EMG provides information about the functions of the stomatognatic system in TMD patients with minimal discomfort and a non-invasive method. 6 Surface electromyography of the masticatory muscles allows an objective distinction between different TMD subgroups and does not support conventional clinical assessments. might help. [7] In the literature, there are studies evaluating temporomandibular disorders and bruxism with EMG, studies examining the correlation between masticatory muscles and subjective tinnitus with subjective and EMG, studies examining the treatment of temporomandibular disorders and bruxism with occlusal splint with EMG. However, subjective tinnitus seen with temporomandibular disorders/bruxism; There are no studies investigating the treatment and management of these diseases. It is presented in discussion. At the same time, the anatomical differences discussed in the etiology of subjective tinnitus associated with temporomandibular disorders/bruxism, and the question of common phylogenetic origin still remain unresolved. In our study, only TMD and TMD+bruxism groups, etiological factor questions and treatment of these diseases, changes in masticatory muscles and the management of subjective tinnitus will be investigated.

In this study, we also; We aimed to treat patients with temporomandibular disorder accompanied by tinnitus with the use of occlusal splint, which is minimally invasive and the most preferred method. At the same time, we aimed to compare the data between the use of superficial EMG and the electrical activity of the masseter muscle, which is the main chewing

muscle, and temporomandibular disorder, bruxzyme, subjective tinnitus, and to elucidate the etiology of subjective tinnitus, which is the subject of discussion in the literature. The use of an occlusal splint is one of the most effective methods in the management of temporomandibular joint disorders and in reducing symptoms such as joint/muscle pain and limitation in mouth opening. With this treatment method, simultaneous treatment of subjective tinnitus seen with the temporomandibular joint is aimed.

Material-Methods Section:

The study will be conducted with patients who routinely apply to Kütahya Health Sciences University Faculty of Dentistry. 70 patients with temporomandibular disease accompanied by tinnitus and bruxism will be included in the study. Demographic data such as age, gender, and systemic disease, drug and trauma history data will be collected.

TMD findings of the patients will be classified according to Wilkes classification. The Wilkes classification is as follows:

1. Stage 1 (early period): No pain or limitation of jaw movements, only reciprocal click during or after chewing. Mild anterior disc displacement in radiological evaluation.

2. Stage 2 (early/intermediate): Mild to moderate pain with reciprocal clicking and periodic locking. Change in disc position.

3. Stage 3 (intermediate): Joint tenderness with frequent pain. Ongoing crash. On the radiological image, changes in disc position and deformation with adhesions.

4. Stage 4 (intermediate/late): Chronic pain that gets worse from time to time and limitation in jaw movements. Change in the shape and position of the disc and the shape of the condyle. Multiple adhesions with hard tissue changes.

5. Stage 5 (late stage): pain that occurs from time to time with crepitation.

Bruxism data (time of onset, whether it is felt during the day/night, fatigue, difficulty in opening the mouth in the morning, stressful period) are questioned and examination findings (disc displacement, masseter hypertrophy on inspection, linea alba, attrition of teeth, fractures in restorations and teeth, muscle and joint pain) , facial asymmetry, mouth opening) will be recorded. The characteristics of tinnitus (objective/subjective, duration, in which ear, increasing and decreasing factors, type) and hearing loss, vertigo will be questioned.

Patients will be divided into two groups. Group I will consist of Wilkes Stage 1-2 patients with temporomandibular intra-articular disorder. Group II will consist of patients with both Wilkes Stage 1-2 temporomandibular intra-articular disorder and bruxism.

In order to measure the muscle strength of the patients before the treatment, in order to reach the chewing muscles easily and to minimize the patient's discomfort, EMG containing right-left M. Masseters will be taken. The analog EMG signal will be amplified using a differential amplifier with a high common-mode rejection ratio (bandwidth 5 KHz, peak-to-peak input range 200 μV). The average of the signals is over 500 ms. (Micromed, Italy)
Superficial EMG will be taken following the following protocol:

- To reduce skin impedance, the skin will be cleaned before electrode placement and recordings will be made after 5-6 minutes.
- Superficial electrodes will be placed on the right and left masseter muscles, with the upper pole of the electrode parallel to the intersection between the tragus-labial commissura and the exocantion-gonion lines. The grounding electrode will be placed in the forehead area.
- For all tests, patients will be seated with their head unsupported and asked to maintain a natural upright position.
- To avoid any effects of fatigue, a rest period of at least 3 minutes will be allowed between tests. The average EMG potential for each of the muscles will be set to 100%.
- To standardize EMG potentials, two 10 mm thick cotton rolls will be placed on each subject's mandibular first and second molars, and maximum voluntary clamping of 5 seconds will be recorded. For 5 seconds, the patient will be encouraged to maintain the same level of contraction. EMG data analysis for all tests, the best 3-s period (the one with the most stable signal) will be automatically selected by the software and used for all subsequent analysis.
- Electromyographic activity will then be recorded with a maximum voluntary squeeze at the intercuspal position; The patient will be invited to squeeze as hard as possible and maintain the same level of contraction for 5 seconds. Electromyographic activity will also be taken again while the patient is at rest.
- For each subject, the EMG potentials of the analyzed muscles recorded during the maximum voluntary clamping tests will be expressed as a percentage of the average potential recorded during the standardization test (maximum voluntary clamping on cotton rolls).
    - (μV/μV×100).
- To assess muscle symmetry, the EMG waves of the masseter muscles will then be compared by calculating a percent overlap coefficient (POC, %). POC is an index of the symmetrical distribution of muscle activity determined by occlusion. The index ranges from 0% to 100%: a POC of 100% will be achieved when two paired muscles contract with perfect symmetry.

Tinnitus and bruxism will be evaluated by the patient with the VAS score. Tinnitus level will additionally be measured with the Tinnitus Handicap Inventory. Then, an occlusal splint will be prepared for the patients. occlusal splints; will be done with canine-protected occlusion and necessary occlusal arrangements will be made before the plates are delivered to the patients. Splints will be manufactured from hard acrylic and personalized measurements will be taken and the model will be prepared and made. It will be recommended to use them for 24 weeks. Postoperative EMG, Tinnitus Handicap Inventory and VAS scores will be re-evaluated after the use of the occlusal splint.

In the light of the data obtained; Age, gender, disease findings, preoperative and postoperative Tinnitus Handicap Inventory, VAS scores, masseter and temporal muscle strength in EMG will be compared and evaluated.

Inclusion criteria:
Patients older than 18 years

Patients with chronic subjective tinnitus

Patients with Wilkes Stage 1-2

Patients with bruxism

Exclusion criteria:
Patients with Wilkes Stage 3-4-5

Patients with tinnitus due to audiological, neurological, metabolic or pathological reasons

Patients with objective tinnutus

Patients with normal tinnitus

Mentally retarded patients

Hearing loss, use of ototoxic drugs

Those with ear diseases such as acute ostitis media, perforated tympanic membrane

Those with Meniere's disease

Patients with middle ear pathology

Those with intracranial pathology

Those with traumatic cervical spine injury

Patients with severe depression diagnosed by a psychologist

Patients who have received TMB treatment in the last two months

Sample Selection: Significance in the G Power analysis program with reference to a previously presented study. When the effect size was taken as 0.08 for the value, it was planned to recruit 70 patients for $\alpha = 0.05$ and 80% power.

Statistical method to be used: All analyzes will be done with SPSS software. In-group temporal evaluations in test and control groups will be evaluated using Pairedsample –T or Wilcoxon test according to normal distribution values. For comparisons between groups, according to the normal distribution of the data, Student-t test will be used for parametric within-group evaluations and Mann Withney U test will be used for non-parametrics. The normal distribution of the data will be evaluated with the Kolmogorov-Smirnov test. The significance value will be taken as 0.05. Relationships between variables will be evaluated with Logistic Regression Analysis or Multivariate Regression Analysis.

Sources List:

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3. C.M. C, G. F, M.J. T, J.T.T. DS. Clinical evaluation of tinnitus in patients with sleep bruxism: Prevalence and characteristics. *J Oral Rehabil*. 2005;32(11):808-814.
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5. Bernhardt O, Gesch D, Schwahn C, et al. Signs of temporomandibular disorders in tinnitus patients and in a population-based group of volunteers: Results of the Study of Health in Pomerania. *J Oral Rehabil*. 2004;31(4):311-319. doi:10.1046/j.1365-2842.2003.01249.x
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