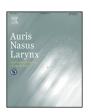
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An improved system for grading and treating tinnitus

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ABSTRACT

Objective: Tinnitus is an auditory sensation that can cause discomfort or even pain. Because patients with tinnitus frequently have psychological problems, self-reporting of the severity of tinnitus is unreliable. We developed a new grading system and practical protocol for the systematic treatment of tinnitus that accounts for its severity, patients' psychological problems, and the frequency of catastrophic episodes. The aim of this study is to employ and validate the new system in patients with tinnitus.

Methods: This study comprised two parts: (i) We identified 113 patients, who were then analyzed in terms of severity of tinnitus, psychological problems, and catastrophic episodes. They were then classified into 5 grades, and the records of their previous treatments were scrutinized. From these records, we designed a practical treatment protocol suitable for each of the 5 grades.

(ii) We then identified 82 new patients, and graded and treated them according to the system developed in part (i). Patients were followed-up for at least 6 months; treatment efficacy was evaluated using the pre- and post-treatment scores on the Tinnitus Handicap Inventory (THI) and Hospital Anxiety and Depression Scale (HADS). Psychological status was also assessed with the DSM-IV.

Results: (i) The overall patient group was categorized as follows: Grade I, 38 patients, average THI = 37.6 points, average HADS = 10.9 points, catastrophic episodes = 0 points; Grade II, 24 patients, THI = 70.6, HADS = 13.1, catastrophic episodes = 0; Grade III, 5 patients, THI = 73.2, HADS = 28.4, catastrophic episodes = 0; Grade IV, 33 patients, THI = 63.5, HADS = 18.8, catastrophic episodes = 1.0; Grade V, 13 patients, THI = 73.2, HADS = 22.4, catastrophic episodes = 2.2. The treatment records revealed treatment via psychotropic drugs for 40% of Grade III, 45.5% of Grade IV, and 84.6% of Grade V patients; psychiatric consultation was provided for 20% of Grade III, 12.5% of Grade IV, and 53.8% of Grade V patients.

(ii) THI scores improved significantly in Grades II, IV, and V after treatment using the new protocol; HADS scores improved significantly in Grades IV and V. Catastrophic episode scores improved significantly in Grades IV and V.

Conclusion: We found large enough differences in THI and HADS scores to successfully classify patients with tinnitus into 5 distinct grades that accounted for tinnitus severity, psychological problems, and catastrophic episodes. We found significant improvements in tinnitus severity and psychological problems in the higher (more severe) grades when this system was used to guide

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treatment. This system not only provided a reasonably reliable categorization system, it simplified treatment without sacrificing efficacy.

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1. Introduction

Tinnitus is a condition in which the patient has a continuous sensation of ringing or other sound in the ears or head, although there is no actual external sound. It is reported that at least 10% of people have experienced tinnitus, and 1–3% of these cases are severe [1]. Tinnitus is frequently associated with sensorineural hearing loss, suggesting that dysfunction of the inner ear or more proximal auditory tracts may cause both tinnitus and perception. However, the specific mechanisms and lesion site(s) in tinnitus remain unclear.

Tinnitus can be bothersome even when not severe, and often interferes with patients' daily living activities. The sensation and severity of tinnitus are also highly variable across patients. Because no mechanism has been verified, treatment of tinnitus is both difficult and very complicated, including modalities such as medication, sound therapy, psychiatric treatment and others.

Recently, Zöger et al. reported that 62% of patients with tinnitus had signs of depressive illness at some point in their lives, and 39% were actively depressed [2]. This suggests that depressive illness can affect tinnitus perception, and such psychological problems may complicate tinnitus treatment. Therefore, tinnitus management must consider both psychological state and the severity of tinnitus sensations. Several tinnitus classifications and guidelines for its management have been proposed; however, there are few practical protocols for tinnitus treatment that consider the psychological background of patients with tinnitus.

To better standardize and improve treatment, we developed a new grading system and a practical protocol for tinnitus treatment that takes into account the severity and psychological backgrounds of patients with tinnitus. The aim of this study is to describe the development and parameters of the new system, and validate it by analyzing its application in a group of patients with tinnitus.

2. Methods

This study is a retrospective clinical data study comprising two separate experiments; the selection of subjects and the methods for each experiment are provided separately below. All patients provided written informed consent for the treatment and publication of their data. Protocols for both experiments were approved by the ethical committees of Nagoya City University (experiment 1: No. 60-16-0148, experiment 2: No. 60-16-0149).

2.1. Experiment 1: development of the new system

2.1.1. Subjects

We analyzed data from 113 patients with tinnitus (63 men and 50 women; mean age 61.1 years old) among patients who visited the outpatient clinic at Nagoya City University Hospital and Kasugai City Hospital from April 2007 to June 2009. All

patients had continuous tinnitus and had been treated for more than 6 months. We determined the severity of tinnitus, psychological background and number of catastrophic episodes for every patient. We excluded the patients who did not fill out all items of the questionnaire.

2.1.2. Grading system

The severity of tinnitus was evaluated with the Tinnitus Handicap Inventory (THI), which was developed by Newman et al. in 1996 [3]. The THI contains 25 questions that use a point scale based on answers of *yes* (4 points), *sometimes* (2), and *no* (0). The total score (0–100 point range) is classified into four categories: 0–16, no handicap; 18–36, mild handicap; 38–56, moderate handicap; and 58–100, severe handicap. In this study, we used only two categories (T1, 0–56 points; and T2, 57–100 points), based on the finding of McCombe et al. that patients in categories 1–3 (up to 56 points) could perform daily activities, whereas patients in the remaining two categories could not [4].

Psychological problems in patients with tinnitus were assessed with the Hospital Anxiety and Depression Scale (HADS), a reliable, well-validated instrument [5,6]. The HADS has 14 items scored from 0 to 3 points each. We classified anxiety/depression in 3 grades according to the HADS total scores [7], as M1 (no anxiety/depression, 0–10 points), M2 (mild anxiety and depression, 11–19 points), and M3 (severe anxiety and depression, 20–42 points).

We included a patient's catastrophic condition in the classification system to consider severe psychological conditions that generally require psychiatric consultation; it was defined as the incidence of a catastrophic event according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for major depression and catastrophic episodes. Catastrophic episodes include: (1) near-daily insomnia; (2) advanced trouble performing activities; (3) failure of human relations; and (4) suicidal desires. We classified catastrophic condition into three categories based on how many of any of the above episodes the patient reported: C0 (no episodes); C1 (one episode); and C2 (2–4 episodes).

Finally, patients were categorized into one of five grades of tinnitus based on the three subscales above (their T, M and C scores). Grade I was defined as T1, M1/M2, and C0; Grade II as T2, M1/M2, and C0; Grade III as any T score, and M3 and C0; Grade IV as any T and any M scores, and C1; Grade V as any T, any M, and C2 (see Fig. 1).

2.1.3. Developing the practical treatment protocol

After classifying the 113 patients with tinnitus into the preliminary five-grade system, we analyzed the medical records of the grouped patients to ascertain their previous treatment. We then developed a practical treatment protocol suitable for each grade of the system by following the guidance of previous reports

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