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## **Abstract**

Objective: 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. 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. 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.

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