

## Tinnitus and Melatonin

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### Page 1

Approximately 15 million Americans have a severe form of tinnitus, the perceived sensation of a ringing, roaring or humming sound without actual acoustic stimulation. Although several theories have been proposed to explain the mechanism of tinnitus, the exact cause for this condition remains unknown; suggested treatments for the condition have not worked well in alleviating the symptoms.

A number of patients with this disorder find the condition debilitating, interfering with work, socialization and sleep. A new study asserts that melatonin use is associated with improvement of tinnitus and sleep. Melatonin is a hormone produced by the pineal gland, known to be involved in regulating the sleep-wake cycle.

The authors of "The Effects of Melatonin on Tinnitus and Sleep," are Jay F. Piccirillo, MD, Uchechukwu C. Megwalu, and Joshua E. Finnell, all with the Department of Otolaryngology—Head and Neck Surgery, at the Washington University School of Medicine, in St. Louis, MO. Their findings appear in the February 2006, edition of *Otolaryngology—Head and Neck Surgery*, the medical and scientific journal of the American Academy of Otolaryngology—Head and Neck Surgery.

### Methodology

This prospective open-label study involved 18 patients between the ages of 18 and 70 who had idiopathic, troublesome, unilateral or bilateral, nonpulsatile tinnitus of six month's duration or greater who sought treatment at the Washington University Department of Otolaryngology—Head and Neck Surgery. The average age of the study subjects was 61 years and the average duration of tinnitus was 11.3 years.

Patients with tinnitus related to cochlear implantation, retrocochlear lesion, or other known anatomic and structural lesions of the ear and temporal bone were excluded from the study. The Tinnitus Handicap Inventory (THI) and the Pittsburgh Sleep Quality Index (PSQI) questionnaires were administered at the beginning of the study. The patients took 3mg of melatonin, one pill, one to two hours before bedtime for four weeks. This was followed by an additional four weeks of observation during which time the patients received no melatonin.

The THI and PSQI were administered at weeks 2, 4, 6, and 8. The independent variable was the administration of melatonin; the dependent variables included the scores on the THI and the PSQI. Primary outcome measures were the changes in THI and PSQI between weeks 0 and 4 and between weeks 0 and 8. The secondary outcome measure was the association between the change in THI and the change in PSQI.

### Page 2

#### Results

The average and median THI score decreased over the eight-week duration of the study. The average and median PSQI score at week 4 decreased from week 0, and the week 8 score was less than week 0. However, coincident with cessation of melatonin, the week 8 score was increased from week 4. There was a decrease in the mean THI score of 6.6 between weeks 0 and 4 and this difference was statistically significant. There was a mean THI decrease of 7.8 between weeks 0 and 8 and this difference was also statistically significant. Neither change score was as great as the predetermined value of 10 for clinical significance, although the upper 95 percent CI did exceed 10 for the difference between week 0 and week 8. There was a mean PSQI decrease of 2.9 between weeks 0 and 4 and a mean PSQI decrease of 2.5 between weeks 0 and 8. These were considered clinically significant since they were equal to or greater than the predetermined value of 2.5.

There was an association between the change in PSQI and the change in THI between weeks 0 and 4. There was no association between the change in PSQI and the change in THI between weeks 0 and 8. The average

change in PSQI among those nine patients who reported a clinically significant decrease in THI (equal to or greater than 10) in the first four weeks was 3.9. There was an association between the PSQI at week 0 and the change in the PSQI in the first four weeks. However, there was no association between the THI at week 0 and the change in the THI in the first four weeks. Melatonin was well-tolerated by all patients. No adverse effects were reported by any of the patients.

### Conclusion

The scores indicated that after taking melatonin there was alleviation of tinnitus symptoms and better quality sleep. Still, the researchers speculate that the changes might not be real or if they are real, whether they are clinically significant. Furthermore, due to a lack of control there is difficulty in establishing a cause and effect between the degree of improvement in tinnitus and the degree of improvement in sleep.

The study suggests that melatonin use is associated with improvement of tinnitus and sleep. The impact of melatonin on sleep was greatest among patients with the worst sleep quality, but its impact on tinnitus was not associated with the severity of the tinnitus. There was also an association between improvements in sleep and tinnitus. This suggests that melatonin may be a safe treatment for patients with idiopathic tinnitus, especially those with sleep disturbance due to tinnitus.

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